

A GLOBAL PERSPECTIVE ON PATENTS AND
EVERGREENING: LESSONS FOR SOUTH AFRICA AS A
DEVELOPING STATE

BY

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SCOPE OF THE MINI – DISSERTATION

The mini dissertation deals with the area of intellectual property with specific focus on patent law evergreening within the context of human rights.

The central issue hinges on how patent law through evergreening affect the affordability of medicines by countries in developing and least developed countries. The effect of evergreening on citizens of developing and least developed countries become central.

Chapter one focuses on the Global Compact, which is an initiative of the United Nations (UN), which on its human rights principles calls upon the business and international institutions e.g. World Health Organisation (WHO), World Trade Organisation (WTO) through the Agreement on Trade – Related Aspects on Intellectual Property Rights (TRIPS), International Monetary Fund (IMF) and World Bank amongst others not to be complicit to human right issues when conducting their business. The chapter gives a compelling case around the issue of Global Compact within the perspective of human rights and fits it squarely on the issue of evergreening which arises from the patent law discipline of intellectual property. A brief definition of the evergreening is spelt out in this chapter. The chapter equally lays down the foundation for analysis of chapters which follow.

Chapter two deals with the South African patent system and evergreening. This involves highlighting the relevant legislations which are applicable to access to health over and above the Patent Laws.

Chapter three focuses on two classic cases from India as the leading nation on compulsory licencing and evergreening in the world dealing with how developing nations can exploit the provisions of the TRIPS Agreement to their benefit and how courts and tribunals in developing and least developed countries can interpret their national laws to give meaning and effect which aligns with their national objectives having regard to their standing in the world. Lessons from the experiences in India are equally explored and consideration on how they may be applied in South Africa in its current regime are considered and recommendations are made.

Chapter four focuses on the role of South African Courts and tribunals in interpreting patent laws within the context of human rights. A selected number of cases are analysed and critiqued focusing amongst other things on whether our courts are contributing to asserting the constitutional right to healthcare as enshrined in the constitution. It is equally explored whether the courts and tribunals are doing enough in this regard or they could do more. The role of the Patents Commissioner, the Supreme Court of Appeals (SCA), the Competition Commissioner, the tribunal, Competition Appeals Tribunal and the Constitutional Court are equally looked at having regard to certain decided cases.

Chapter five focuses on draft national policy on intellectual property of 2013 and the intellectual property consultative framework of 2016. Following the intended overhaul of the Intellectual Property regime to among other reasons align it with the National Development Plan (NDP) and the need to align the Patent Act with the TRIPS obligations coupled with the need to address the effects of evergreening, certain provisions of the draft national policy and consultative framework documents are analysed, commented upon and critiqued.

Chapter six deals with the role of civil society groups in promoting access to healthcare. Special focus is on patent laws and access to medicines and drugs. It is demonstrated that civil society groups through lobbying, protests, submissions to stakeholders including

Government and international bodies as well as through court cases play a pivotal role in promoting the right which ultimately benefit the poor and needy members of the society.

Chapter seven deals with reflections, conclusions and recommendations. Although the conclusions, reflections and recommendations are extractable and permeate throughout the chapters in this contribution, only a non-exhaustive few are mentioned as part of the conclusion and recommendations to the contribution.

It concludes by inviting the reader after going through all the chapters to revert back where the reader began, i.e. the first quotation of the contribution, which is equally the first footnote of the contribution.

CHAPTER ONE

INTERNATIONAL PERSPECTIVE OF PATENT LAW WITHIN THE CONTEXT OF BUSINESS AND HUMAN RIGHTS

1. INTRODUCTION:

"The idea of a better ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death." ¹

The United Nations (UN) is leading the charge in an endeavour to inculcate a culture of human rights by encouraging the infusion thereof by various businesses both within their jurisdictions and globally.

The UN Global Compact was announced by the then secretary General of the United Nations, Kofi Annan at the World Economic Forum in Davos on 31 January 1999. Its operating phase was launched on 26 July 2000 at the UN Headquarters in New York.

A quote in Annan's promotional brochure of the Global compact reads:

- Let us choose to unite the power of markets with the authority of universal ideals.
- Let us choose to reconcile the creative forces of private entrepreneurship with the needs of the disadvantaged and requirements of future generations. ²

The Global Compact is premised on the ten principles of the better world.

The UN Global Compact's Ten Principles are derived from the Universal Declaration of Human Rights, the International Labour Organization's Declaration on Fundamental Principles and Rights at Work, the Rio Declaration on Environment and Development, and the United Nations Convention Against Corruption.

Of relevance to this contribution are the principles focusing on human rights. Principles 1 and 2 provide: Human Rights: Principle 1: Businesses should support and respect the protection of internationally proclaimed human rights; and Principle 2: make sure that they are not complicit in human rights abuses.

¹ Gandhi I, *World Health Assembly*, 1982.

² William O The UN Global Compact: The Challenge and the promise © 2004. Business Ethics Quarterly, 14 (4) 757.

These principles are relevant in that they hinge on the core of business and human rights central to which is pharmaceutical companies and the protection of intellectual property through the Agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS) and other means on the one hand and developing countries endeavouring to protect their citizens in fighting for affordable medicines on the other, arguing against evergreening as a method of maintaining the *status quo* to the disadvantage of their citizens as it affects affordability of medicines which is essential for health.

Professor Ernest Ulrich Petersmann (Petersmann), in his article³ writes the following important abstract: "The 'Global Compact', launched by UN Secretary-General Kofi Annan in 1999, calls upon business to 'support and respect the protection of international human rights within their sphere of influence and [to] make sure their own corporations are not complicit in human right abuses'. This article call for complimentary 'Global Compact' between the UN and UN specialised agencies, as well as with other worldwide public organisations such as the World Trade Organisation (WTO), so at to integrate universally recognised human rights into the law and practice of intergovernmental organisations, for example by requiring them to submit annual 'human rights impact statements' to UN human rights bodies and to engage in transparent dialogues about the contribution by specialized agencies to the promotion and protection of human rights. The globalization of human rights and of economic integration law offers mutually beneficial synergies: protection and enjoyment of human rights depend also on economic resources and on integration law opening markets, reducing discrimination and enabling a welfare-increasing division of labour. As a corollary, economic, legal and political integration are also a function of human rights protecting personal autonomy, legal and social security, peaceful change, individual savings, investments, production and mutually beneficial transactions across frontiers. The proposed 'integration approach' differs from the 1945 paradigm of 'specialized agencies' and state-centred international law focusing on the 'sovereign equality' of states rather than on human rights and democracy. It takes into account the regional experiences in Europe, that integration law enhances not only economic and social welfare but also the rule of law, protection of human rights and democratic legitimacy at national and international levels of governance. As in European integration law, human rights should be recognised in global integration law as empowering citizens, as constitutionally limiting national and international regulatory powers, and as requiring governments to protect and promote human rights in all policy areas across national frontiers. Global integration law (e.g. in the WTO) should no longer focus one-sidedly on liberalization. It should also accept shared responsibility for the social adjustment problems of the global division of labour and for governmental obligations to protect and promote human rights in the economy no less than in the polity." ⁴

This abstract is more telling on the trends which are being adopted as a departure from the experiences of the past economic agencies of the world and the approach of national issues

³ Time for United Nations 'Global Compact for Integrating Human Rights into law of Worldwide organisations: Lessons from European Integration statics (2002),13(3) 621 – 650.

⁴ Idem 621 -622.

around 1945. It emphasises the fact that there should be material departure from the past. Going forward, the policies of liberalisation should not take centre stage and be oblivious of the need to ensure that human rights are upheld and protected.

The field of Intellectual Property (IP) and patent law for purposes of this contribution is one of the fields which are directly impacted by the “Global Compact” for integrating Human Rights into the Law of Worldwide Organisations. The World Trade Organisation (WTO) is among the worldwide public organisations which is expected to comply with the Global Compact insofar as it relates to ensuring that human rights are protected and upheld and that they are integrated in the laws which apply to it in various forms in particular given that it has business in the centre of its core.

The debate around patent law and how it affects human beings who are affected by inadequate or lack of access to drugs for health treatment has been ongoing and continues to be an issue within the sphere of access to health particularly affecting developing and least developed countries, although not limited to them. Petersmann quotes WM Corden, Trade Policy and economic welfare (1974) and WK Viscusi, JM Vernon and JE Harrington Economic Regulation and Antitrust (2nd edition, 1997) and correctly points out that the proposed change from international functionalism to constitutionalism does not put into question the economic efficiency arguments for “optimising and separating policy instruments”.⁵

The learned author goes further to state European integration confirms that the collective supply of public goods (such as the global division of labour) may not be politically feasible without ‘package deals’ including solitary responses to market failures and redistributive ‘principle of justice’. He notes interestingly that less developed countries, for instance, often perceive market competition as a “licence to kill” for multilateral corporations from developed countries as long as liberal trade rules are not supplemented by completion and social rules (as in the EC) promoting fair opportunities and equitable distributions of gains from trade⁶.

The learned author painstakingly points out ⁷ “In order to remain democratically acceptable, global integration law (e.g. in the WTO) must pursue not only ‘economic efficiency’ but also ‘democratic legitimacy’ and ‘social justice’ as defined by human rights. Otherwise, citizens will rightly challenge the democratic and social legitimacy of integration of law if it pursues economic welfare without regard to social human rights, for example the human right to education of 130 million children (aged from 6 to 12) who do not attend primary school; the human basic right to basic health care of 25 million Africans living with AIDS, or of the 35,000 children dying each day from curable diseases; and the human right to food and adequate standard of living for the 1.2 billion people living on less than a dollar a day. The

⁵ Idem 636 Par 3.

⁶ Idem 623 par 3 - 624 par 1.

⁷ Idem 624 par 1.

new opportunities for the worldwide enjoyment of human rights created by global division of labour such as additional economic resources, job opportunities, worldwide communication systems, and access to new medicines and technologies) must be accompanied by the stronger legal protection of social human rights so as to limit abuses of deregulation (e.g. by international cartels, trade in drugs and arms, and trafficking in women and children), help vulnerable groups to adjust to change without violation of their human rights, and put pressure on authoritarian governments to protect not only business interests but also the human rights of all their citizens.”

Through TRIPS there has been strides made in an endeavour to strike the balance between the long term social objective of providing incentives for future inventions and creation, and the short-term objective of allowing the use of existing inventions and creations. While the issue pertaining to patents and pharmaceuticals are covered by the TRIPS agreement, there is a wider spectrum of laws within the realm on intellectual property covered by the agreement.⁸

In the eyes of the protagonists of human rights in IP Law, this “licence to kill” manifests itself through evergreening in patent laws.

Evergreening refers to: “a variety of legal, business and technological strategies by which producers extend their patents over products that are about to expire, in order to retain royalties from them, by either taking new patents (for example over associated delivery systems, or new pharmaceutical mixtures), or by buying out or frustrating competitors for longer periods of time than would normally be permissible under the law”.⁹

“Evergreening is not a formal concept of patent law. It is best understood as a social idea used to refer to the myriad ways in which pharmaceutical patent owners utilise the law and related regulatory processes to extend their rent-earning intellectual monopoly privileges, particularly over highly profitable (either in total sales volume or price per unit) block buster drugs. Thus, while the Courts are an instrument frequently used by pharmaceutical brand manufacture’s tactical use of pharmaceutical patents (including over uses, delivery systems and even packaging), not to extension of any particular patent over an active produce ingredient”.¹⁰

The structural set up of various institutions which were expected and continue to be expected to advance world social and international order as envisaged in Article 28¹¹ of the Universal Declaration of Human Rights (UDHR) 1948 are clearly spelled out by Petersmann¹² under the

⁸ See WTO OMC FACT SHEET (September 2006) 1.

⁹ See Faunce T “The awful truth about ever greening” presented at conference on European Policy on Intellectual Property on 6 August 2004.

¹⁰ See Faunce T and Lexchin J Australia and New Zealand Health Policy, 2007 at 1.

¹¹ “Everyone is entitled to a social and international order in which rights and freedom set forth in this declaration can be fully realised.”

¹² Idem 622 at par 2.

heading “Introduction: Time for Reconsidering the ‘Washington Consensus’ and for Strengthening Human Rights in Global Integration Law”

It covers among other role players the UN, IMF, WTO, World Bank, ILO and specialised agencies such as UNESCO (The United Nations Educational, Scientific and Cultural Organization) and WHO (World Health Organization).

The genesis of the problem which is the subject matter of this mini dissertation can be extracted from Petersmann when he states “Apart from a few exceptions (notably in ILO, UNESCO and WHO rules) human rights were not effectively integrated into the law of most worldwide organisations so as to facilitate functional international integration (such as liberalisation of trade and payments); notwithstanding different views of governments on human rights and domestic policies (such as communism).¹³

It is worthy to note that there has been a shift in the scope and recognition of rights from the traditional civil and political rights towards the recognition and acceptance of so called second generation rights which are now the central theme to this contribution.

The Regional integration law however has shifted from the paradigm linking economic integration to constitutional guarantees of human rights, democracy and undistorted competition.

The author further poses a very important question whether the European and Free Trade of America (FTAA) “integration paradigm” should also not be accepted at the worldwide level in order to promote a new kind of global integration law based on human rights and the solidarity sharing of the benefits and social adjustments costs of globalisation integration.¹⁴

It is submitted that this question as put here and differently elsewhere should be answered in the affirmative for a plethora of reasons which will be covered in various stages of chapters in this contribution.

More importantly for South Africa, as a developing state, the writer states “Less developed countries, for instance, often perceive market completion as a “licence to kill” for multinational corporations from developed countries as long as liberal trade rules are not supplemented by competition and social rules (as in EC) promoting fair opportunities and equitable distribution of gains from trade.”

¹³ Idem 662 Par 3 – 623 Par 1.

¹⁴ Idem 623 Par 3.

The writer further states:¹⁵ “In order to remain democratically acceptable, global integration law (e.g. in the WTO) must pursue not only ‘economic efficiency’ but also ‘democratic legitimacy’ and ‘social justice’ as defined by human rights. Otherwise, citizens will rightly challenge the democratic and social legitimacy of the integration law if it pursues economic welfare without regard to social human rights, for example the human right to education of the 130 million children (aged from 6 to 12) who do not attend primary school; the human right to basic health care of the 25 million Africans living with AIDS, or of the 35,000 children dying each day from curable diseases; and the human right to food and adequate standard of living for the 1.2 billion people living on less than a dollar a day. The new opportunities for the worldwide enjoyment of human rights created by the global division of labour such as additional economic resources, job opportunities, worldwide communication systems, and access to new medicines and technologies) must be accompanied by the stronger legal protection of social human rights so as to limit abuses of deregulation (e.g. by international cartels, trade in drugs and arms, and trafficking in women and children), help vulnerable groups to adjust to change without violation of their human rights, and put pressure on authoritarian governments to protect not only business interests but also the human rights of all their citizens.”

The effects of prioritisation of business interest with profit as a motive to the detriment of the majority of the people, in particular those of the underdeveloped and developing countries by making the sale commodities not accessible due to exorbitant or unaffordable prices is inimical to the envisaged infusion of the human right component on global trade policies.

The initial emphasis of the so called first generation rights as was propagated to represent the tenets of the universal declaration of human rights and in the process relegating other basic rights, e.g. education and healthcare to the back banner did not assist or rather constituted a delay towards implementation of human rights in particular with specific relation to institutions which are playing in the trade market and also thrive in unjust competition by e.g. by protecting their patents through what has become known as “evergreening “

In 2002 its report on Integrating Intellectual Property Rights and Development Policy, the Commission on Intellectual Property Rights¹⁶ noted the following: -

“We are aware of the importance of effective patent protection for the industry most directly involved in discovering and developing new pharmaceuticals. Indeed, without the incentive of patents it is doubtful the private sector would have invested so much in the discovery or development of medicines, many of

¹⁵ Idem 624 Par 2.

¹⁶ Integrating Intellectual Property Rights and Development Policy, Commission on Intellectual Property Rights, 2002.

which are currently in use both in developed and developing countries. The pharmaceutical industry in developed countries is more strongly dependent on the patent system than most other industrial sectors to recoup its past R&D costs, to generate profits, and to fund R&D for future products. Successive surveys have shown that pharmaceutical companies, more than any other sector, think patent protection to be very important in maintaining their R&D expenditures and technological innovation. The industry understandably takes a close interest in global application of IPRs, and generally resists the contention that they constitute a major barrier to access or a deterrent to development in developing countries. For instance, Sir Richard Sykes, the former Chairman of GSK, said in March this year:

“Few would argue with the need for IP protection in the developed world, but some question whether it is appropriate to extend its coverage to the developing world, which the TRIPS agreement is gradually doing. As I have said, IP protection is not the cause of the present lack of access to medicines in developing countries. At Doha last November, WTO members agreed to defer TRIPS implementation for the least developed countries until 2016. I do believe that TRIPS will prevent other developing countries like Brazil and India from obtaining access to the medicines they need. On the other hand, I firmly believe that these countries have the capacity to nurture research-based pharmaceutical industries, as well as other innovative industries, but this will only happen when they provide the IP protection that is enshrined in TRIPS. TRIPS need to be recognised as an important industrial tool for developing countries.”¹⁷

“That said, we are fully aware of the concerns expressed by, and on behalf of, developing countries about the impact that such rights may have in those countries, particularly on prices of pharmaceuticals. If prices are raised, this will fall especially hard upon poor people, particularly in the absence of widespread provision for public health as exists in most developed countries. Thus, others from many developing countries, and the NGO community, have argued the opposite:” “Why do developing countries object so strongly to TRIPS? Its essential flaw is to oblige all countries, rich and poor, to grant at least 20 year’s patent protection for new medicines, thereby delaying production of the inexpensive generic substitutes upon which developing – country health services and poor people depend. And there is no upside: the increased profits harvested by international drug forms from developing - world markets will not be ploughed back into extra research into poor people’s diseases – a fact some companies will in private admit.”¹⁸

“Our starting point in this analysis is that healthcare considerations must be the main objective in determining what IP regime should apply to healthcare products. IP rights are not conferred to deliver profits to industry except that these can be used to deliver better healthcare in the long term. Such rights must therefore be closely monitored to ensure that they do not actually promote healthcare

¹⁷ Presentation by Sir Richard Sykes at the Royal Institute of international Affairs, London, 14 March 2002.

¹⁸ *Oxfam (2001) “Priced out of Reach”, Oxfam Briefing Paper No.4, Oxfam International Oxford, Source <http://www.oxfam.org.uk/policy/papers/priced/priced.html>.*

objectives and, above all, not responsible for preventing poor people in developing countries from obtaining healthcare”¹⁹

The above extracts from the Commission report and authors cited therein clearly demonstrate the two contrasting views on promoting Intellectual Property Rights on the one hand and Human Rights to Healthcare on the other. The views expressed in these contradictions will be critiqued in various chapters to follow.

It is submitted that the extracts equally demonstrate the impediment of the task which was faced by the commission in its quest among others being how to consider whether and how Intellectual Property Rights (IPRs) could play a role in helping the world meet the targets of the Millennium Developing Goals by reducing poverty helping combat disease, improving the health of mothers and children, enhancing access to education and contributing to sustainable development.²⁰

2. CONCLUSION

The above extracts as cited among others in this contribution constitute the hallmark of the changes which are taking place along the lines of what is envisaged through the ‘Global compact’ and the analysis thereto in this contribution will implicitly permeate through as and when the subject matter is being critiqued herein.

These elaborative quotations were aimed at cutting a clear picture of the ongoing international debate on Patent law protection and human rights with specific reference to access to health.

The clear move towards recognition of constitutional human rights, which leads to the benefits of better access to healthcare among other rights is clearly not free from contestation which will be demonstrated in various ways in the following chapters.

¹⁹ Report on Intellectual property 2002, page 29-30.

²⁰ See overview on 1 par 3.

CHAPTER TWO

THE SOUTH AFRICAN PATENT SYSTEM AND EVERGREENING

1. INTRODUCTION AND COMMENTS

There is no single legislation in South Africa, which independently deals with issues which may be affecting access to health in South Africa. A variety of legislations either independently or complementing each other are relevant to asserting a constitutionally entrenched right.

Legislators can play a pivotal role in giving the courts the proper tools for interpretation and move away from the dogmatic approach of interpretation, e.g. literal meaning and infusing the Constitutional Culture should be permeating through.

In his article titled “After the *Novartis* judgement – evergreening will never be the same again,²¹ Vawda proffers the view that the leading Indian case on evergreening i.e. the *Novartis* case could not have come more handy for South Africa as it is grappling with the new intellectual Property law. The author has written more elaborately on the lessons which South Africa could draw from this judgement as it has the potential of assisting in the coining of legislation relevant to the concern generally raised about the exploitative nature of pharmaceutical (multilateral) companies on developing nations in particular the endeavours to use the TRIPS Agreement in particular adherence thereto as a measure of ensuring that patent concepts like evergreening are used to perpetuate the commercial exploitation of patented products beyond their patented period.

2. SOUTH AFRICAN LEGISLATIVE FRAMEWORK

Each of the legislations mentioned below has a role to play and through interpretation, it may find its way in contributing to the jurisprudence of access to healthcare which is a constitutional right enshrined in Section 27 of the Constitution of the Republic of South Africa, 1996.

The South African Constitution (the constitution)²² is the cornerstone of democracy which everyone is expected to abide by.

²¹ See Page 6 Par 2.

²² Act 106 of 1996.

In chapter 1 of its founding provisions, the constitution²³ provides: “The Republic of South Africa is one, sovereign, democratic state founded on the following values:

- (a) Human dignity, the achievement of equality and the advancement of human rights and freedoms.
- (c) Supremacy of the Constitution and the rule of law.

In chapter 2, the Bill of Rights, section 9 deals with equality and provides: -

- (1) Everyone is equal before the law and has the right to equal protection and benefit of the law.

Section 10 which deals with human dignity provides: “Everyone has inherent dignity and the right to have their dignity respected and protected.”

Section 11 provides that “everyone has the right to life”.

Section 25 which is known as the property section provides:

- (1) No one may be deprived of property except in terms of the law general application, and no law may permit arbitrary deprivation of property.
- (4) For purposes of this section,
 - (b) property is not limited to land.

Section 27 of the constitution which deals with healthcare, food, water, social security provides:

- (1) everyone has the right to have access to:
 - (a) health care services, including reproductive health care;
 - (b) sufficient food and water; and
 - (c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.
- (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
- (3) No one may be refused emergency medical treatment.

Section 39 which deals with the interpretation of the Bill of Rights provides: -

Interpretation of Bill of Rights 39.

- (1) When interpreting the Bill of Rights, a court, tribunal or forum—
 - (a) must promote the values that underlie an open and democratic society based on human dignity, equality and freedom;
 - (b) must consider international law; and
 - (c) may consider foreign law.

²³ See Section 1

- (2) When interpreting any legislation, and when developing the common law or customary law, every court, tribunal or forum must promote the spirit, purport and objects of the Bill of Rights.
- (3) The Bill of Rights does not deny the existence of any other rights or freedoms that are recognised or conferred by common law, customary law or legislation, to the extent that they are consistent with the Bill.

The list of relevant provisions of the Constitution for the purposes of this contribution are not exhaustive. Those mentioned herein have been identified as some of the provisions which have a role or scope to play in any jurisprudential contribution relevant to access to healthcare which is the central theme of the contribution. They will be used in developing submissions around patent laws in South Africa as a developing country.

The other legislations which are relevant to the question of access to medicine in South Africa are the Patents Act²⁴, the Medicines Control and Related Substances Act²⁵ as amended, and the Competition Act²⁶.

In chapter four discussing the case law analysis in promoting access to healthcare from the patent law perspective in this contribution, the provisions of the legislations mentioned in this chapter will be, analysed and critiqued on how courts arrived at decisions. The Constitutional provisions will equally be looked at, analysed and critiqued with the same objective.

To this end, provisions of section 39(1) and (2) as mentioned above, are a very important guideline of what the Courts must and may do when interpreting a bill of rights. There is a clear injunction on our courts to consider international law and a discretion to consider foreign law. This is preceded by the injunction to the effect that a Court, tribunal or forum must promote the values that underlie an open and democratic society based on human dignity, equality and freedom. The case of the *Treatment Action Campaign v Minister of Health* discussed in chapter four demonstrate this aspect.

The Medicines Control and Substance Act, in particular Section 15C thereof, has contributed immensely in the *PMA and Others v President of RSA & Others* case which attracted a worldwide attention and culminated in the withdrawal of the case following worldwide protests led by lobby groups and the intervention through engagement with the Secretary of the United Nations. This case is equally discussed in chapter four.

The Competition Act has equally contributed through among others the case of *Hazel Tau and others v Glaxo Smith & Boehringer Ingelheim (Pty) Ltd.*²⁷ The interpretation of the Act and the

²⁴ Act 57 of 1978.

²⁵ Act 101 of 1965.

²⁶ Act 89 of 1998.

²⁷ Competition Commission – Case No. 2002 Sep 226.

culmination outcome of the complaint is discussed in Chapter four and six which deal with the role of the Courts, tribunals and civil society organisations in interpreting and asserting the issue of access to medicines in South Africa.

There are many cases which flow from the Patents Act of which the *Cipla* case is but one of many. It will later be critiqued on whether the case of *Cipla* is a lost opportunity by South African Courts in ceasing the moment and addressing the issue of access to health care in South Africa, whether the courts should be taking it upon themselves. While this matter is relevant in chapter four, it is dealt conveniently with in chapter six.

In their contribution to the topic “Using the Law to accelerate treatment access in South Africa: An analysis of Patent, Competition and Medicines Law, commissioned by the United Nations Development Programme, 2013, Chan Park, Aclinal Prabhala and Jonathan Berger remark: -

“The case law makes it clear that the obligation to respect, protect, promote and fulfil the right to have access to medicines rests on the state as a whole, not just a single department. In South Africa, responsibility for IP Law and Policy falls under the Department of Trade and Industry and responsibility for competition law and policy falls under the Economic Development Department. In dealing with health issues in general including Patent laws within the context of human rights, there is an absolute need to harmonise the three pieces of legislation so as to effectively ensure the realisation of the right to access to health as enshrined in the constitution.”²⁸

The learned authors aptly examine the extent to which the domestic legal and regulatory environmental enabled countries in Africa to increase access to essential medicines by specifically focusing on South Africa.

In their article, citing the WIPO’s, statistical country profiles, it is revealed that the vast majority of patents applications in South Africa are filed by foreign entities. This means that more patent applications are filed by non-resident entities than resident entities.

This may be attributed to the flexible process of application for patents in South Africa which does not entail a rigorous process envisaged elsewhere in other jurisdictions where there are stringent requirements for patentability.

The provisions of section 25 of the Patents Act which lay down the basic requirements for patentability provide: -

²⁸ See Intellectual Property Consultative Framework, 2016 at page 12, See also Park et al “Using Law to accelerate the treatment access in South Africa: in Analysis of Patent competition and medical law”, UNDP, 2013 at 14.

“A patent may, subject to the provisions of this section, be granted for any invention which involves an inventive step and which is capable of being used or applied in trade and industry, or agriculture.”

Regulation 41 of the Patent Regulations, 1978 respectively provides: -

Examination

41. The registrar shall examine the application accompanied by a complete specification in order to ensure that it complies with the prescribed formalities

Regulation 44 of the Patent Regulations, 1978 respectively provides: -

Acceptance

44. As soon as the registrar is satisfied that an application accompanied by a complete specification complies with the requirements of the Act, and unless there has been a request to delay acceptance, he may accept the application and give written notice thereof which shall be accompanied by form P 8.

The Patent Act is currently so flexible insofar as it relates to the process of granting a patent. Applications are made and appropriate forms filled, fees paid and the patent grantor just grant same without any rigorous scrutiny.

Park Prabhala and Berger note the limitations of the free granting of the patents without any rigorous scrutiny and strict patentability criteria by grantor of patent.

They cite the US case of *KSR int'l v Teleflex Inc.*²⁹, where the US court observed “Granting patent protection to advance that would occur in the ordinary course without real innovation retards progress, and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility”.

They therefore remark that setting the bar higher for obtaining a patent will result in a few better quality patents while fewer patents will result in greater generic competition, which will in turn lower drug prices as well as ensure sustainable supply of these drugs from multiple manufactures while at the same time expressing the opinion that higher patentability criteria will also result in real incentive for research and development.

It is clear from the foregoing that in its quest of dealing with the issue of access to health and healthcare, the amendments of the IP Policy and the enabling legislation presents itself with an opportunity for Government to amend the provisions relating to the requirements for patentability in that there are real benefits in doing so even from the flexibility requirements of TRIPS in particular South Africa’s obligations under Article 27.1 which provides: “ Patents shall not be made

²⁹ 550 U.S 398 (2007) at page 15.

available for any inventions , whether product or processes, provided that they are new, involve an inventive step and are capable of industrial application”

The opportunity does not limit itself to TRIPS compliance. It also presents an opportunity for constitutional compliance with Section 27 and also an opportunity for legislators to deal adequately and decisively with the issue of evergreening.

3. CONCLUSION

In this chapter, it is clear that the constitution, the Patents Act, the Medical Control and Substance Act and the Competition Act are the relevant legislations dealing with the issue of access to medicine. The impact of pharmaceutical companies in preventing the realisation of this objective through “evergreening” derives its argument from the TRIPS Agreement under the guise of protecting Intellectual Property Rights (IPR). The Patents Act in particular is very relevant to evergreening as discussed extensively on its efficacy in this chapter and subsequent ones. All the Acts and their roles are elaborately dealt with in chapter four and the Competition Act extensively in chapter six.

CHAPTER THREE

INDIA'S PATENT CASES AND ACCESS TO MEDICINE

1. INTRODUCTION

Following the relaxation of the stringent measures which were encapsulated in the TRIPS Agreement through the Doha Declaration, India as a developing country took major steps which were aimed at among other things ensuring its compliance with the TRIPS Agreement, as one of the member states of the WTO.

Most importantly, in its quest for compliance, India used the provisions of the Doha Declaration in its endeavours to ensure that it aligns its domestic legislation with the quest for access to medicines for its people and even ensuring that it contributes in the importation of medicines to other countries who are in dire need for generic medicines. By the same token, the Courts in India have played a very magnificent role in their interpretation of the applicable patent legislation domestically and having regard to the applicable and relevant international instruments.

The courts and tribunal decisions from India, as will be discussed below ably demonstrate the impact they have made internationally in contributing to world's jurisprudence inextricably affecting all nations.

With enabling legislation being correctly and courageously interpreted, the courts in India have aptly demonstrated how courts of law can contribute to their jurisprudence on issues which have a universal effect and consequently giving a model which may be followed by other developing countries who are affected by the impediment of access to affordable drugs which are patented by pharmaceutical companies and perpetuated through "evergreening".

This chapter will analyse the impact of two highly celebrated cases, which were decided upon by the High Courts in India and the lessons which can be drawn by South Africa as it is grappling with the issues of access to medicine and health in general. While the two cases are by no means an answer to the big problem afflicting developing countries in relation to access to health, it is submitted that through its legislative framework in relation to the patent where it affects access to health, India has played a magnificent role contributing to the promotion of access to health for its citizens through legislation by legislatures, adjudication by tribunals and court judgments delivered by the judiciary. The in depth analysis of the aforementioned arguments are dealt with hereunder.

Two classic cases emanating from India will be discussed hereunder:

2. BAYER CORPORATION VS NATCO PHARMA LIMITED

One of the much-celebrated cases to emanate from India relating to Patent Law interpretation by Courts following the TRIPS Agreement is the case of *Bayer Corporation vs Natco Pharma Limited*.³⁰ It is recorded as a matter of fact as the first compulsory licensing (CL) case to be heard under the TRIPS agreement.

The background leading to this landmark decision by the Indian Courts is that the legislators in India amended the Patent Act, 1970, at least three times in the post-TRIPS era, to facilitate product patent protection. These amendments were made in 1999, 2002 and 2005 respectively.

As Professor K.D Raju (Raju) puts it in his article³¹ "India sought to comply with the grace period which had been accorded to developing and least developed countries to enact their patent legislations which would have an effect of "compulsory licensing" in line with what is expected of countries in particular developing countries with the ultimate effect of benefiting their citizens with generic medicines therefore promoting public health in their domestic countries".

"Intellectual property protection has been an old age practice to recognise creative innovations of the inventor (Gilbert & Shapiro, 1996). The protection regime under the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement made exclusive rights to the patentee for limited period of time, that is, 20 years. It provides minimum standards to be complied with by the 161 World Trade Organisation (WTO) member countries. But misuse of the monopoly power cannot be tolerated by society especially when it affects public interest and in the case of fighting life-threatening diseases like cancer. CL provision was incorporated in the TRIPS Agreement as an antidote to monopoly power granted to the patent holder. If the voluntary licenses are refused by the patentee, there is no choice than to issue a CL complying with the grounds clearly mentioned in the present TRIPS Agreement, which is a practice followed much before the general Agreements on Tariffs and Trade (GATT), 1947."

As aptly put by Raju³² "It is important to note that Compulsory Licenses are issued when a Government allows someone else to produce the patented product or process without the consent of the patent owner."

It is equally important to note that issuing of compulsory licenses *per se* does not take away the rights of the patent owner as certain rights including being reasonable compensation for

³⁰ *Natco Pharma Limited V Bayer Corporation*, Indian Patent Office, C.L.A.No.1 of 2011 (12 March 2012).

³¹ The first Compulsory Licence case under the TRIPS Agreement: an Analysis of *Bayer V Natco Pharma Ltd* Journal of Development policy and Practice 1(1).

³² See page 7 par 2.

using his or her invention. The word compulsory licensing is not defined anywhere. The home page of WTO however simply define compulsory licencing as where a government allows someone else to produce the patented produce or process without the consent of the patent holder.³³

Following the Doha Declaration, which was adopted at the Interministerial Conference in Doha in 2001, the TRIPS Agreement provides flexibility for national governments to fine tune the provisions in accordance with their social and public health policies.

In *Bayer Ltd vs Natco Pharma*, a case which went through various stages of litigation including the Controller of Patents, The Delhi High Court, Intellectual Property Appellate Board, the Bombay High Court and the Supreme Court of India is a clear demonstration of how pharmaceutical companies (*Bayer* in this instance) will go all the way in an attempt to protect their intellectual property rights and ousting competition through evergreening and venturing to go against the grain of compulsory licencing as envisaged in the TRIPS Agreement in particular Article 31 thereof.

In this regard, Raju writes:

“Even though the judgement of the IPAB has been described briefly here, it is discussed elaborately on what constitutes public interest and what the legislative intent of Section 84 is. Welfare of society is supreme and monopoly and economic interest of a multinational company cannot be replaced with protecting public health. The letter and spirit of the TRIPS Agreement allows the member states to use leeway allowed under the agreement, thus India never violated any of the provisions of the TRIPS Agreement in granting CL to an Indian generic company against a multinational drug major. The Doha declaration permits exports of such drug to countries with insufficient manufacturing facilities in the pharmaceutical sector as an exception to Article 31(f) of the TRIPS Agreement (RAO, 2006).”³⁴

While comments regarding the High Court of Bombay and the Supreme Court of India will follow hereunder, it is apposite to highlight the intense way which the institutions (IPAB in *casu*) went to analyse the provisions of the International Agreement and apply its domestic laws to give meaning and effect through a leverage which is being accorded by the international agreement to benefit society through a public health legislation where ordinarily, there would be a deprivation of a benefit based on lack of affordability and consequently impeding on a socio-economic right of access to health.

³³ See WTO.org (Compulsory Licencing).

³⁴ See Raju Page 81 par 2.

The fact that the IPAB did not agree with the controller that working in India under section 84(1) (c) would only be complied with when the patented drug is manufactured in India and proffered the view that importing of the drug can also satisfy this criterion if the manufacturing is not possible in India, was a noble and extensive interpretation which had a positive effect of promoting access to drugs in the public interest. It made a cherry on top by finding that manufacturing was therefore not necessary to comply with section 84(1) (c) of the Indian Patent Act.

The laborious and well-reasoned manner with which the Bombay High Court dealt with the challenge in this matter brought under Article 226 of the Constitution of India are equally ground breaking.³⁵

After the lodging of an appeal with the Supreme Court of India, through a special leave petition, the matter was dismissed on the grounds that it was prematurely brought before the Supreme Court of India, while the Appeal could still be heard by the IPAB. What Raju correctly points out when he says “But this is considered to be victory for the access to medicine activists and the first CL issued passed the preliminary test of all appellate jurisdictions”.³⁶

From the foregoing, it is clear that the utilization of the provisions of applicable international agreements (TRIPS Agreement in *casu*, in particular the provisions of Article 31) through ensuring that as an affected country you put relevant legislative measures in place, and ensure that measures are consistent with the international agreement. When confronted by the need to apply the local domestic law, you can through relevant institutions, including tribunal and courts be able to assert the legitimate rights of your citizens and ensure that they are protected through ensuring that they enjoy access to basic the right to medicine which they would not ordinarily enjoy as a result of the use of competition laws under the guise of protection of intellectual property rights.

In his conclusion of analyzing the First Compulsory Licensing case of *Bayer vs Natco Pharma*, Raju concludes as follows³⁷:

“The Indian CL case should be seen as a model by all developing countries in issuing CL in the future. The fusion of intellectual property rights and moral rights to protect the interest of

³⁵ See Raju 81 -83.

³⁶ See Raju 83 Par 2.

³⁷ See Raju Page 85.

the public should be balanced in all CL cases so that it passes the litmus test of domestic law as well as the rules of TRIPS Agreement and a review by the dispute settlement body of WTO.”

I share the sentiments expressed by Raju and submits that South Africa, as one of the developing countries and largely affected by diseases including TB and HIV, should take cue and draw lessons from India on how it has used the law as an instrument to contribute to the pursuit of access to rights through justice.

Noting the bully tactics by the big pharmaceutical companies, sometimes assisted by countries like the United States of America (USA), Raju notes ³⁸the apparent reluctance of the USA in taking up the matter with the WTO Settlement System and using its “Special 301 Report” on India as a basis of cajoling developing nations from effectively utilizing their domestic laws to achieve results which are beneficial to their citizens right of access to medical drugs.

This view holds for as long as the big pharmaceuticals and their supporters are genuinely willing to engage and subscribe to the bigger international bodies ideal of infusing human rights within the ambit of intellectual property regime. This can be done in many ways e.g. by being receptive to the idea of the request for a voluntary license by application for the purpose of production of generic drug as was the case by *Natco*.

The receptive nature by the big pharmaceuticals will result in either the curtailing of or minimizing evergreening which they are generally involved in and consequently extending the span of protection of patent right which is always detrimental to manufactures of generic medicines and consequently affecting the affordability of drugs by members of the public or their respective governments. This will be so if the CL holder’s capacity to produce the drug is limited after being granted the CL.

3. NOVARTIS VS UNION OF INDIA & OTHERS

The landmark case on the topic of evergreening which has attracted worldwide attention in the case of *Novartis AG v Union of India & Others*.³⁹

This case is of high significance in the whole world in matters relating to the protection of patents rights by big pharmaceutical companies as holders of original patents rights (who

³⁸ See Raju Page 85.

³⁹ See Civil Appeals Nos 2706-2716, 2728 and 2717-2727 of 2013 Supreme Court of India.

are sometimes protected by their countries of origin) and developing and least developed countries, sometimes aided by activist lobby groups (which are advocates of human rights in particular on access to health for the purpose of this contribution).

It has a very rich history as a *compectus* or prism which is a model for other developing and least developed countries on how the introduction of a domestic patent legislation which is aimed at aligning itself with the provisions of TRIPS Agreement to which a country belongs and is bound by may be utilized to realize the objectives of contribution to access to health for its citizens, while acting within the framework and ambit of the international agreement to which the country is a member.

Importantly, the case is a catalyst as a point of reference in that developing countries faced with similar challenges of access to health drugs for their citizens and how they may ensure that the right is exercised in a manner which does not violate their International Agreement on TRIPS but complies with Article 31 of the Agreement.

The decision in this case serves as a litmus test on how to approach and deal with the needy countries and big pharmaceuticals seem not to have a sense of appreciation on the lamentation of developing countries in their quest to curb the developed practice which is popularly known as “ever greening” and practiced by patent holders and perpetually elongating the lifespan of the original patented drug and consequently stifling competition which the producer of generic medicine would give in the market after the original patent period would have lapsed.

The interpretation of applicable national legislation was passed having regard to the provisions of article 31 and consequent to the 2001 Doha Declaration interpreted by the Supreme Court to give recognition to the plight of developing nations to the effect that nothing prevents developing nations from enacting health legislations which have a net effect of promoting access to health for its citizens.

It is respectfully submitted that the developing and least developed countries, will immensely benefit from the provisions because their inability based on constrains of resources to manufacture generic drugs, will be ameliorated by these provisions in that access to medicine at an affordable rate from the production of generic drugs manufactured in a national licenced patent, will be able to be imported to them at a lower price than it would ordinarily be the case in the event the patent remained extended through “evergreening” in the hands of the original patent holder.

Before dealing with the implications of the judgement to developing states, it is important to comment on some issues raised by the court before handing over the judgement.

The Supreme Court of India heard three appeals simultaneously. One of the Appeals was brought by the *Novartis AG*, the international pharmaceutical company, the Second Appeal was brought by *Natco Pharma Ltd*, a local generic drug manufacturing company while the third appeal was brought by an independent group which formed an association to aid cancer patients called M/S Cancer Patients Aid Association.

It is further interesting to note that all the appellants in these three matters brought their respective appeals against the Union of India and Others as the Respondents.

Furthermore, the second and third appellants were successful in their appeals whereas the first appellant (Novartis) which is a giant Swiss International Pharmaceutical company and a member of the International Federation of Pharmaceutical Associations (IFPMA) lost in its endeavours of evergreening.

In this case the facts as sourced from the Supreme Court judgement can briefly be summarised as follows:

After filing a patent application which lay dormant under the arranged “mailbox procedure”, *Novartis*, made an application for exclusive marketing rights for the subject product under Section 24A of the Act. The application for marketing exclusive rights was made while the application for patent was taken up for consideration. The application was done during the transitional stage of patent law in India. The patent office did grant exclusive marketing rights by an order dated 10 November 2003.

The taking of patents application out of the “mailbox” for consideration, was done after the amendments to the Patents Act were made. The consideration of the patents was fiercely met by pre-grant opposition by various respondents including but not limited to *M/S patients Aid Association and Natco Pharma Ltd*.

The matter including the pre-grant objections was heard by the Assistant controller of Patent and Designs, whose orders were challenged by *Novartis* as the appellate authority under the Act had not yet become functional. *Novartis* therefore filed the petitions to the Madras High Court.

Most significantly, *Novartis* filed two writ petitions seeking a declaration of section 3(d) of the Indian Patents Act to be unconstitutional and violating Article 14 of the Indian Constitution and also not in compliance with the TRIPS Agreement of which India was one of the member states.

Following the introduction of the IPAB, the writ petitions challenging the five orders of Assistant controller of the Patents and Designs were transferred from the Madras High Court to the IPAB.

The IPAB heard the matter including petitions hence the Appeal of its decisions which were considered by the Supreme Court of India, which were brought through a petition under Article 36 of the Constitution notwithstanding the fact that the issues were open to being ventilated by the High Court before they could be considered by the Supreme Court.

What stands out in this consolidated case is the clarity on interpretation of domestic law of patents which the role players including the Assistant Controller of Patents and Designs, the IPAB and finally the Supreme Court of India interpreted legislation and considered an International Agreement to arrive at a bold and watershed decision which has an international impact on the issues related to access to medicine as it affects the developing and underdeveloped countries.

The lessons which South Africa can draw from the experience flowing from this watermark decision are important taking into account the recent developments which are yet to be realised regarding the change in patent law to accommodate the reality of access to medicine.

It is important to cite few quotes from the findings by the Supreme Court to illustrate the scrutiny and application of domestic law by the role players. The Court ⁴⁰ said

“..... The IPAB, however, held that patentability of the subject product was hit by section 3(d) of the Act. Referring to section 3(d) the IPAB observed “Since India is having a requirement of higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable on other countries will not be patentable in India. As we see the object of amended section 3(d) of the Act is nothing but the requirement of higher standard of inventive step in the law particularly for the drug and pharmaceutical substances”.

The Judgement further reads:⁴¹

“the IPAB also referred to the judgement of the Madras High Court, dismissing the appellant’s writ petition challenging the constitutional validity of Section 3(d) where the high Court has observed: “We have borne in mind the object which the amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to the citizens of the country to life saving drugs and to discharge their constitutional obligation of providing good health care to its citizens”.

⁴⁰ See *Novartis Judgement* Par 17.

⁴¹ See *Novartis Judgement* Par 18.

Vawda notes that as at the time of publishing his article, on the Novartis Judgement “as a matter of record, no compulsory licence had ever been issued in South Africa in respect of a pharmaceutical product.”⁴² This still remains the position in South Africa to date and has been acknowledged in the intellectual Property Consultative Framework document as approved by Cabinet on 6 July 2016.⁴³

South Africa lags behind as it failed in grabbing opportunities which have presented themselves through the TRIPS Agreement aimed at contributing in promoting access to health through the area of patents in particular the benefits which can be utilised for the production of generic medicines for the benefit of the poor at affordable prices.

As one of the areas which South Africa can benefit from Indian experience, Vawda mentions the strengthening of the compulsory licencing provisions to extend them to instances where reasonable requirements of the public with respect to the patented invention have not been satisfied, or the patented invention is not available to the public at a reasonably affordable price.

4. CONCLUSION

It is respectfully submitted that the judiciary and the tribunal in India has once more played a crucial role in laying the basis and model which may be followed in other jurisdictions when the interpretation and application the law for the benefit of citizens are at stake.

To achieve this, there must be an enabling legislation which when read with a right enshrined in the constitution will have the effect of ensuring that the right to healthcare is addressed within the context of IP and human rights.

The Courts and Tribunals in India , through their various stages or levels until the Supreme Court have served as catalysts for change by using the TRIPS Agreement as a source for interpreting the applicable domestic law resulting in change which benefits of its citizens through access to affordable generic medicines.

⁴² See page 11 footnote 65.

⁴³ Intellectual Property Consultative Framework at 9-12.

CHAPTER FOUR

THE ROLE OF SOUTH AFRICAN COURTS AND TRIBUNALS IN INTERPRETING PATENT LAWS IN THE CONTEXT OF HUMAN RIGHTS

1. INTRODUCTION

In this chapter, an assessment will be made to establish how our courts and tribunals have through their decisions contributed towards access to health of the citizens, which is a constitutional imperative. If not, what role if any, they can play.

A general overview will be made on the approach of courts when dealing with interpretation of a statute insofar as it may have an effect on affecting the rights of individuals, in particular the constitutionally entrenched right to health in this instance.

While there continues to be a demonstrable push by various international and local lobby groups to ensure that the field of Intellectual Property is not used as a means to hamper access to health for the majority of the population largely based in developing countries, there has equally been orchestrated moves by pharmaceutical industries, sometimes with the aid of their states to undermine the goal of global access to health. Profit has been a motive behind ensuring the maintenance of the *status quo*.

In South Africa, pharmaceutical companies used various ways including courts of law to block initiatives by the Government aimed at advancing a constitutional imperative of working towards a progressive realisation of access to health.

2. COURTS

One of the most classical cases to demonstrate this point is the case of *Pharmaceutical Manufacturers Association of South Africa v The President of the Republic of South Africa and Others*.⁴⁴

In *casu*, the Government of the Republic of South Africa introduced and passed an amendment to the Medicines and Related Substances Control Amendment Act.⁴⁵ This legislation introduced parallel importation and compulsory licencing as mechanisms to

⁴⁴ Case No.4183/98.

⁴⁵ Act. 90 of 1997.

improve access to medicines by providing for the importation and manufacturing of cheaper medicines. In this regard Lonias Ndlovu,⁴⁶ notes the following:⁴⁷

“Although the South African Government strenuously denied that the pertinent provision covered compulsory licences, a literary reading of it clearly shows that compulsory licences were contemplated”

He further states “The Act was verily criticised by the international pharmaceutical industry, the United States (of America), and the European Union before it was enacted.”⁴⁸

As part of the argument, it should be noted that the Association argued that the provisions of Section 15C,⁴⁹ dealing with measures to ensure supply of more affordable medicines “was in violation of the TRIPS Agreement and the South African Constitution, in that they were too vague since they involved a restriction of patents rights, this being a *prima facie* violation of property rights in section 25 of the Constitution. It was further argued that the impugned legislation violated Article 27 of TRIPS in that it discriminated against patent rights in the pharmaceutical field (*a submission which Bombach submits would not have been won had the matter proceeded to finality in the litigation given the provisions of Article 31 and Article 6 of the TRIPS Agreement providing for compulsory licencing and parallel imports respectively*)

⁴⁶ Access to medicines under the world trade organisations TRIPS agreement: a Comparative Study of select SADC Countries, submitted in accordance with the requirements of the degree of Doctor of Laws, University of South Africa, 2014.”

⁴⁷ See footnote 317 on page 203

⁴⁸ See Bombach “Can South Africa fight Aids? Reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement (2001) *Boston University Journal* 274 -305.

⁴⁹ Section 15 of the Medicines and Related Substance Act 101 of 1965 provides the following: The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-

- (a) notwithstanding anything to the contrary contained in the Patent Act 1978 (Act 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent.
- (b) prescribe the conditions on which any medicine which is identical in composition meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacture as approved by council in the prescribed manner may be imported.
- (c) prescribe the registration procedure for, as well as use of the medicine referred to in paragraph (b)

The author further notes correctly as a matter of fact “the Matter was viewed in a very serious light by the US Government, which put South Africa on the special section 301 watch list of countries that deny an effective intellectual property protection, with the justification that South Africa’s placement on the list is due to the fact that the Act gave the Minister ill-defined authority to authorise and potentially otherwise abrogate intellectual property rights.

It should be noted that the admission of the Treatment Action Campaign (TAC), as *amicus curiae* in the matter, the international pressure mounted by various lobby groups and the obtaining of around 300 000 (three hundred thousand) signatures demanding the withdrawal of the case against the South African Government ignited unbearable pressure on the pharmaceutical companies, culminating in their withdrawal of the case subsequent to the mediation efforts of the Secretary General of the UN, who is the pioneer of the Global Compact whose provisions are clear and unequivocal as to the direction which the UN would like principle 1 and 2 to take and the impact thereof insofar as it would be relevant on access to medicine, among other rights.

Ndlovu further notes “in 2001 the South African Government and the Pharmaceutical industry pledged to work together, with the government affirming its commitment to the TRIPS and its willingness to consult with the pharmaceutical industry in the formulation of regulations to Section 15C. Subsequently, the US President issued an executive order forbidding the US from seeking a revision of intellectual property laws of sub-Saharan African states that promote access to the HIV/AIDS pharmaceuticals but are TRIPS compliant.”⁵⁰

I agree with the author on the enormous impact which this case has had on the international agenda relating to the TRIPS Agreement and access to health. The same goes to how bad the pharmaceutical companies and their supportive countries were exposed in their apparent non-committal to ensuring the importance of access to health. The case is further mentioned in chapter six dealing with the role of civil society groups in promoting access to healthcare.

From this case the following observations are made:

1. The United States and European Union, although signatories to the TRIPS agreement and being bound by its provisions, strive to find ways to use the law of Intellectual Property to find “fault” of non- compliance with the Intellectual Property Regime within the TRIPS Agreement with the apparent purpose of safeguarding an interest which if properly scrutinised will not pass the muster of the Agreement insofar as it relates to developing countries from the perspective of access to medicine.

⁵⁰ See Hester Meyer Human Rights and the WTO: The case of Patents and Access to medicines (2007) 16.

2. The Pharmaceutical Companies did not have any sustainable argument having regard to the provisions of article 31 of the TRIPS Agreement and Article 6 of the TRIPS Agreement which provide: ⁵¹
3. The Government of South Africa was equally caving in to the Pharmaceutical Companies in that it could not boldly argue that pertinent provision i.e. Section 15 (C) covering compulsory licences. This is so notwithstanding the fact that a literary reading clearly shows that compulsory licences were contemplated, is equally not inimical to the express provisions of Article 31 of the TRIPS Agreement. This has subsequently been confirmed in the first compulsory licencing case of *Bayer v Natco Pharma Ltd* in India which is elaborately discussed in chapter 3 of this contribution.
4. The Government's expression of willingness to consult with the pharmaceutical industry in the formulation of regulations to section 15C is partial capitulation in that in an open and accountable democracy, there is no need for special invitation to stakeholders or interested parties to comment on regulations which give practical effect to a legislation on regulation. This could still be done in the ordinary course of processes affecting enabling

⁵¹ *Article 31: Other Use Without Authorization of the Right Holder*

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as is practically possible. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly....."

Article 6: Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

legislations on regulations. To put it conversely, all stakeholders, interested parties and anyone is entitled to comment on either legislation or regulations as and when they are called upon to do so before being put into effect by the empowered body in terms of applicable processes.

5. This is one of the most important cases in which the Government (executive and legislature) and civil society group's reaction were helpful in bringing to the fore the plight of developing and least developed countries into the world map and has contributed in drawing attention to countries of the world in particular developed ones through the businesses which they may be supporting that it goes against the grain of social justice to boldly and barefacedly argue for an economic right to trade with profit as a motive and trumping the right of access to health as envisaged in the 'Global Compact' among other sources.

In the case of *Minister of Health & Others v Treatment Action Campaign and others*⁵², which is a classical case before the Constitutional Court in which the role of the Court in relation to socio-economic rights in particular relating to section 27(1) and 27(2), a lot of important issues were considered and clarified.

The Court rejected the contention that its powers are limited to issuing of a declaratory order. The Court further stated that where necessary, the appropriate relief may include both issuing of a mandamus and the exercise of a supervisory jurisdiction.⁵³

The Constitutional Court further invoked the discretionary provisions of section 39(1) (C) of the constitution when considering foreign case law under comparable circumstances. It considered the Indian Courts, US Supreme Court, German Federal Constitutional Court, Supreme and Lower Courts and House of Lords in the United Kingdom. The Court found that it has both mandatory and structural interdicts. Although international law in terms of the peremptory provisions of section 39(1)(b) was considered in this matter, it did not fully find relevance for the purposes of determination by the court.

In their contention, applicants sought to use the "minimum core" concept, which was developed by the United Nations Committee on Economic, Social and Cultural Rights (CESCR) to argue that section 26 and 27 give two separate obligations to the state, the contention which after careful consideration, was rejected by the court. [CESCR General Comment 3 "The nature of states parties' obligations (Art .2, par.1)" 14/12/90 para 10. One is mindful of reference having been made on the

⁵² 2002 (5) SA 721 (CC).

⁵³ See Par 106.

Worlds International Conference on AIDS, Durban 2000 and reference to WTO and its attitude towards the safety and efficiency nevirapine.

The Court reaffirmed the justiciability of socio-economic rights. In this instance this relates to Section (1) and (2) which deals with access to health care and by extension access to drugs and medicines.

The court said the following: “Implicit in this finding is that a policy of waiting for a protracted period before taking a decision on the use of nevirapine beyond research and training sites is also not reasonable within the meaning of Section (2) of the Constitution.”⁵⁴

In dealing with the doctrine of separation of powers, the court had the following to say in paragraph 98:” This court has made clear on more than one occasion that although there are no bright lines that separate the roles of the legislature, the executive and the courts from one another, there are certain matters that a pre-eminently within the domain of one or another of the arms of government should be sensitive to and respect this separation. All arms of government should be sensitive to and respect this separation. This does not mean, however, that courts cannot or should not make orders that an impact on policy.”⁵⁵

The following submissions are made regarding the court findings and observations made above in the context of patent law and access to medicines:

1. It is submitted that in rejecting the contention that the powers of the courts are not limited to the granting of declaratory order, this will give a scope for the courts to exercise their powers, when interested parties e.g. lobby groups bring a class action to assert the right regarding patent laws and the rights of access to medicine, within the context of the “Global Compact, TRIPS Agreement and access to medicine. Our courts, in particular the Constitutional Court have not closed its doors on dealing with the matter as envisaged in the provision of section 165(2) of the Constitution.”⁵⁶
2. Our Courts have not and will not hesitate to invoke the provisions of section 39(1)(a)(b) and (c) as well as (2) of the constitution.

So, IP which Patent Law is part of is not immune from these provisions. Consequently, if a relevant case is brought for adjudication and the interpretation of section 27, clashes with section 25, the Court will consider these provisions when developing the jurisprudence. In reaffirming the justiciability of socio-economic rights in terms of Section 27 of the Constitution, it is submitted that notwithstanding the current limitations of our IP Law, the courts, tribunal or

⁵⁴ See Par 84 at 46.

⁵⁵ See Par 98.

⁵⁶ Section 165(2) of the constitution provides: “The courts are independent and subject only to the Constitution and the law, they must apply impartially without fear, favour or prejudice”.

forum should interpret the case in terms of the provisions of section 39 brought despite the limitations.⁵⁷

It is submitted that drawing from the quotation made in paragraph 81 regarding the finding that a policy waiting for a protracted period before taking a decision on nevirapine beyond research and training sites having been found to be not reasonable within the meaning of Section 2 of the Constitution, a similar argument could be made by the apparent delay by Government on the overhaul of the IP Law in general and Patent law in particular for the purpose of this.

While it could be argued that there are cases which aptly demonstrate Government's willingness to address Patent Law and Human right issues, it is open for lobby groups, using an appropriate case to push Government to deal with policy in this regard without further delay. The reasons to that are very noble and profound in that the exploitation of the vulnerable citizens in society continues unabated, while there is apparent complacency on the part of Government. If Government, were to invoke the prioritisation of Patent Law to assert and demonstrate political willingness to the spirit of the Global Compact, Millennium Development Goals, aligning IP Law (Patent Law) with TRIPS and promulgating legislation which can benefit from TRIPS Agreement, this would go a long way in entrenching the Constitutional Right as envisaged in section 27 and also dealing with finding the balance with competing right of immaterial property right.

If there are legislative provisions which flow from the contemplated IP regime change which are one way or the other found to be falling foul of the Constitution, our Courts may beyond be interpreting them to be in line or not in line with the Constitution, not hesitate to declare them to be invalid.

This case undoubtedly illustrates that our courts, in particular, the Constitutional Court will not only make findings against big pharmaceuticals if they are denying citizens the right of access to health using TRIPS provisions and other methods, but courts equally will not hesitate to make declarations and orders against the Government if it conducts itself in a manner which either from a legislative or policy perspective is found to be inimical to the constitution. This submission is strengthened by what the court said in the case of *Government of the Republic of South Africa v Grootboom*.⁵⁸ "The state is required to take reasonable legislative and other measures. Legislative measures by themselves are not likely to constitute Constitutional Compliance. Mere legislation is not enough. The state is obliged to act to achieve the intended result, and the legislative measures will invariably have to be supported by appropriate, well directed policies and programmes implemented by the Executive. These policies must be reasonable both in their conception

⁵⁷ See S39 Interpretation of Bill of Rights in chapter 2.

⁵⁸ 2001 (1) SA 46 at par 42.

and their implementation. The formulation of a programme is only the first stage in meeting the state's obligations. The programme must also be reasonably implemented. An otherwise reasonable programme that is not implemented reasonably will not constitute compliance with state's obligations."

The case of *Soobramoney v Minister of Health, Kwazulu- Natal*⁵⁹ is the first to deal with enforcement of socio-economic rights and access to health through licence applications for the right to manufacture generic drugs in particular in the South African constitutional dispensation. Except for confirming the general justiciability of socio-economic rights and access to health in this instance, the case does not offer much on the issues which could be argued from a patent and human rights perspective. Though it dealt with rationing of healthcare, it can be argued that Government in its patent reform process can look at how the reforms are adjusted to improve the reasonable accommodation of the needs of its citizens so that health equipments and products are affordable and therefore improving access to health.

The recognition of the need to work towards the realisation of access to health in this case were aptly captured by Chaskalson P (as he then was when he said):

"We live in a society in which there are great disparities in wealth. Millions of people are living in deplorable conditions and in great poverty. There is a high level of unemployment, inadequate social security, and many do not have access to clean water or adequate health services. These conditions already existed when the Constitution was adopted and a commitment to address them, and to transform our society into one in which there will be human dignity, freedom and equality, lies in the heart of our new constitutional order. For as long as these conditions continue to exist that aspiration will have a hollow ring"⁶⁰

One of the poignant questions asked by Vawda regarding *Cipla Medpro (Pty) Ltd v Aventis Pharma SA & Others v Cipla Life Sciences and others*⁶¹ is the commitment of South African Courts finding favourably on the granting of compulsory licencing, when the circumstances of the case so warrant.

In his article, after the *Novartis* judgement 'Evergreening will never be the same again!', the learned author remarked as follows: " There are, in addition to the above, other "flexibilities" that South Africa can write into law, draw from experiences in India and elsewhere." ⁶² The judiciary, for example, can also take a leaf out of the book of Indian Supreme Court, which as it demonstrated in the *Novartis*

⁵⁹ 1998 (1) SA 765 (CC)

⁶⁰ See Page 770/771 para 8

⁶¹ 2013 (4) SA 579 (SCA)

⁶² See footnote 63 of the article that provides "These include parallel importation under the international exhaustion regime; several permissible exemptions from patentability, as well as exceptions for research, early working and other purposes; and the freedom to exclude data exclusivity rules which bar drug regulators from referencing clinical trial data already on file, and consequently blocking generic competition. These aspects are treated extensively in the literature."

case, has not been averse to considering public policy arguments in interpreting and applying Patent Law.

In contrast, South African Courts have missed opportunities to break ground in this regard. A case in point is the recent decision of the Supreme Court of Appeal involving the cancer drug “Docetaxel.”⁶³ While essentially against an alleged infringer, this was a significant test case for the extent to which Courts are required to apply broad constitutional principles. In this case, the right of access to healthcare, services and medicines in IP disputes. The Court accepted an *amicus curiae*’s submission that the broader public interest, and not merely interest of the litigating parties, ought to be considered in determining the balance of convenience on the facts of that case.⁶⁴

While making a concession to the principle, the Court took a rather narrow view of the issue of awarding damages (royalties) should the patent ultimately be found to be valid- holding that this would be tantamount to granting a compulsory licence.⁶⁵ Such an approach is indicative of a reluctance of South African Courts and patent authorities to countenance the grant of compulsory licences and is out of step with other jurisdictions, such as India and the USA.”⁶⁶

An analysis of the case and the views of Vawda brings to the fore the following submissions regarding the *Cipla* case: -

The provisions of Chapter III of the patents Act No. 57 of 1978, in particular sections 17,18 and 19 thereof, indicate that the Presiding Judge *a quo*, who assumes the status of the Commissioner of patents sits in the patents proceedings as a Court of first instance, enjoying the status of High Court and using similar procedure as the High Court would ordinarily use and apply.

Although the patents related proceedings deal with specialist issues *per se*, and the practice is almost similar elsewhere, it may be argued that the vigilance of the activist’s groups on matters arising from the Patents office may, of course, depending in the kind of matters heard by the Patents Commissioner, not be attracting the vigilance which manifest itself in places like India by both the lobby groups as well as domestic manufactures of generic drugs and medicines. In both *Bayer v Natco Pharma* and the *Norvatis* cases (discussed in chapter three) , there has been an active participation by these advocate to access to health, of course for different but close reasons from the commencement of proceedings.

⁶³ Footnote 64 of the article cites “Cipla Medpro (Pty) v Aventis Pharma SA, Aventis Pharma SA & Others v Cipla Life Sciences (Pty) Ltd & Others 2013 [4] SA 579 [SCA].

⁶⁴ See page 315 par 4 – page 316 par 1.

⁶⁵ On footnote 65 of his article he notes: As a matter of record, no compulsory licence has ever been issued in South Africa in respect of a pharmaceutical product.

⁶⁶ On footnote 66, he notes: For a fuller discussion of this case, see Gray, Vawda & Jack (2013) at 12/13.

Although the proceedings of the Commissioner of patents are as open as proceedings in an open Court, it appears they may have not attracted enough attention or interest for the lobby groups and local manufactures of generic drugs in South Africa, if there is any with respect to the latter.

In *casu*, the *amicus curiae*, TAC only made an application as such at the second and final leg of the hearing i.e. at the SCA. Although the Court pronouncements regarding the issues raised by the *amicus curiae* in the matter may not have been extensively taken further as suggested by Vawda, the very positive pronouncements by the SCA, although arguably falling short on the extent to which Courts are required to apply broad constitutional principles, should be welcome for the following reasons amongst others: -

1. The SCA had to consider an application for admission as an *amicus curiae* for the first time and duly granted same, the benefit which the judge *a quo*, who sat as a Commissioner of the Patents never had and would have possibly entertained and considered.
2. The court admitted the *amicus curiae* and also made constitutional findings in embracing broader public interest and not merely the interests of the litigating parties in determining the balance of convenience on the facts of that case. It may be true that in not going further, when it came to the granting of damages, the court and patent authorities indicate the countenancing of compulsory licence. The opposite could equally be argued that our Courts will be careful not to be seen to be intruding in cases brought before them for adjudication in the circumstances where the litigants have specifically prayed for a specific order.
3. In this particular case, it is submitted that the SCA would not have seen it fit to fully come with an order on a matter which the parties to the dispute did not seek. The question is, given the role of an *amicus curiae* as generally understood, should our courts in the understanding of their need to apply broader constitutional principles go to the extent of giving an order in line with the submissions of the *amicus curiae*? Perhaps, it may be argued that the court may not have been in a proper space for interference, as an *amicus curiae*, unlike an intervening party, who for all intents and purposes, when admitted as such, may have a finding for or against it and with appropriate costs order, where applicable.

However, in line with Vawda's sentiments, I note the reference to TAC's article mentioned in the South African Medical Journal wherein the following is stated:

"the challenge of evergreening in SA was highlighted in recent litigation over patents held on the popular birth control pill containing drospirenone and ethynyl oestradiol, sold by pharmaceutical company Bayer as Yasmin. The initial 20-year period of patent protection on this medicine ended in 2010 in SA. However, secondary, evergreening patents prevented generic versions from being brought to the

market at a 30% price reduction when the initial patent expired. The Supreme Court of Appeal in Bloemfontein upheld Bayer's secondary patent in 2014, which means that generic use may continue to be blocked until 2024. Generic versions are already available in the USA and countries in Europe following rejection of Bayer's secondary patent in these countries"⁶⁷

These sentiments cannot be brushed aside. A genuine cause of concern is being raised. The attitude of our courts when looking at the position of developed nations as mentioned above calls for proper consideration of IP cases where the human right of access to healthcare is in issue, as was the case in *casu*. It becomes more apt that they do so if developed countries have rejected secondary evergreening patents while a court in a developed country has failed to do so.

Having said that, it is respectfully submitted that the principle regarding public interest as brought by the TAC in this matter was affirmed and entrenched and will serve as a precedent in the future when applications either as an *amicus curiae* or an intervening party appear before the Commissioner of patents, a tribunal or the SCA.

Having regard to the provisions of Section 19 of the Patents Act, it is submitted that given the powers enjoined to our courts in terms of section 172 of the Constitution and given the provisions of s39(1) of the Constitution, an appropriate case regarding IP (Patent Law) and Human Rights may find its way directly to the Constitutional Court for confirmation on invalidity if the judge *a quo*, in the form of the Commissioner of patents declared certain provisions of the enabling legislation to be inconsistent with the Constitution.

This is one of the ways which, appropriate facts, the process of expediting of the transformation of IP Laws could be achieved through court pronouncements although this may only take shape in a piece meal form and consequently defeating the greater objective of promoting the object, spirit and purport of the Constitution, which the Constitutional Court has demonstrably not shied away from.

In the case of *Synthetha (Pty) Ltd v Jannsen Pharmaceuticals N v another*⁶⁸, the SCA upheld the decision of the Commission of Patents in the *court a quo* on the basis that on the face of the founding papers before the court, the appellant had failed to make out a case for the granting of a license. It is submitted that the issues relating to the granting of the CL during that period though applicable was not as much heated an issue as it has become subsequent to developments arising out of the Doha Declaration.

⁶⁷SAMJ, S. Afr. Med. J. Vol. 105 n.9 Cape Town Sep. 2015, at 1 par 8 – at 2 par 1.

⁶⁸ Case 449/96 heard on the 11 September 1998 and judgement delivered on 21 September 1998.

Although not suggesting that the Court should have decided differently, it is noted with regret that in *Pharma Dynamics (Pty) Limited V Pharma AG60* that the court reflected on the Broad principles of patent interpretation as established by authority in a manner outlined below:

Firstly, the court remarked correctly that having considered foreign judgements which were brought to its attention by both parties to advance their respective cases, helpful as the foreign cases could be on matters of law, the court could not derive guidance from them on issues of fact.

What stands out however is that at least, foreign case law relevant to issues of law were considered although it was found not to be of assistance on issues of facts on which a decision was to be made.

The Court borrowed from an old case of *Genticuro AG v Firestone (Pty) Ltd* 69 where Trollip JA said ‘..... [T] The rule of interpretation is to ascertain not only what the inventor or patentee had in mind, but what the language used in the specification means, i.e. what his intention was as conveyed by the specification, properly construed since he is presumed to have intended what his language means. To ascertain that meaning of words used must be read grammatically and in their ordinary sense..... The specification like any other document must be read as a whole.’

The Court went further and cited what was said in the *Cipla* case at para 14 thereof.

The Court then cited Corbett JA, as he then was in *Multitotech Manufacturing (Pty) Ltd v Screenex Wire Weaving Manufactures (Pty) Ltd*⁷⁰

Lastly in para 9 the court said ‘..... Accordingly, in order to enable the court to construe the specification properly, it must be instructed by expert witness as to the state of the art in the field of invention in order to place the court as near as possible to the position of those skilled members of the public to whom it is addressed, as at the relevant date (see e.g. *Sappi Fine Papers (Pty) Ltd v JCI Canada Inc. (formerly CIL INC)* 1992 (3) SA 306 (A) at 3181-319E).

This case also did not, possibly based on facts go anywhere closer to demonstrating that the interpretation of patents laws will be going towards the direction of human rights perspective. This may be attributed to the fact that no constitutional issue was raised in the matter and the case did not involve a generic manufacturing company overtly fighting for a patent right of access by application which would block evergreening.

Similarly, it was not an access to medicine case brought by lobby groups or Government fighting for the rights of citizens invoking provisions which would render the asserting right possible.

⁶⁹ 1972 (1) SA 589 (AD) at 614 B – H.

⁷⁰ 1983 (1) SA 709 A at 721 CE.

3. TRIBUNALS

The other method in which the issue of access to drugs can be dealt with is through the provision of the Competition Act 89 of 1998.

Through this avenue, a complainant is able to lodge a statement of complaint to the commission invoking the provisions of 49B (2) (b) of the Competition Act 89 of 1998.

This was done in the case of *Hazel Tau and Others v Glaxosmith, Boehringer Ingelheim*⁷¹. In this matter, complainants including COSATU and TAC were cited as part of the complainants from the beginning.

In terms of paragraph 17 of the complaint, the complainants allege that the companies that the subject of this complaint have engaged in exercise pricing of ARVs to the detriment of consumers, as prohibited by S 8(a) of the Competition Act, 89 of 1998 resulting in predictable and avoidable death of the people living with HIV/ AIDS, including both children and adults.

As a specialist area of practice, the Competition Act provides for a tribunal as well as the Competition Appeals Court.

With the advent of developments through the Constitution's 17th Amendment Act and the Superior Courts Act 10 of 2013, a party may appeal directly from the Competition Appeals Court directly to the Constitutional court, without the matter going through the Supreme Courts of Appeal. This is so among other reasons due to the fact that the Constitutional Court is an apex Court on all matters in the public which comes before it.

It is submitted that issues of access to healthcare and medicines among other issues which find their way through the Competition Commission, tribunal and Competition Appeal Court may ultimately find their way to the Constitutional Court, more expeditiously than was the case in the old dispensation, which required an appeal to SCA before a matter could be heard by the Constitutional Court.

Although not much utilised, the jurisprudence against anti-competitive behaviour dealt with through the provisions of the Competition Act, will equally assist in contributing to the ideals of the Global Compact principles 1 and 2. Consequently the quest of progressively working towards the realisation of access to drugs by developing countries through the countenancing of evergreening and maintaining the *status quo* through exploiting the gaps created by the slow action in bringing the overdue and much desired change in Intellectual Property regime may equally be minimised.

⁷¹ (competition Commission) Case No 2002 Sept.226.

In the *Hazel Tau* case, subsequent to a settlement agreements reached between complainants and pharmaceutical companies, the complainants withdrew their complaints following the concessions made by the pharmaceutical companies.

This is one of the much celebrated achievements by both the Competition Commission (Tribunal), acting in terms of the Competition Act and particularly for the various complainants led by Hazel Tau. The settlement agreement had far reaching positive implications for the people in that it assisted in securing affordable life-saving antiretroviral medicines.

This settlement serves as a living example of how preliminary findings by a tribunal may lead to settlement resulting in a comparatively expeditious resolution of disputes than would normally be the case in protracted processes of litigation as is normally provided.

It further serves as an example to demonstrate the power of individuals, civil society groups including public interest groups using the available avenues and mechanisms to assert their constitutional rights of access to affordable healthcare in this instance.

The latter is relevant to the role played by individuals, civil society groups and public interest institutions as discussed in chapter six.

4. CONCLUSION

It is clear from the above that the South African Courts and tribunals, in the midst of clear limitations of the Patents Act, the slow pace by legislators to bring legislative reforms on Intellectual Property regime coupled by clear failures of the current Act and failure to utilise express provisions of the TRIPS agreement to the advantage of the country do contribute towards giving meaning and effect the spirit, purport and objectives of our Constitution and thus contributing to both the objects of the Millennium Development Goals and the Global Compact in particular the human rights principles.

It is further aptly demonstrated that other legislative provisions i.e. Medicines Control and Substance Act, Competition Commission Act read with the constitution are being individually and collectively utilised to promote the constitutional objectives and gains derived from the Doha declaration through the TRIPS agreement. The above happen amid failures which have been identified in the Cipla judgement.

CHAPTER FIVE

DRAFT NATIONAL POLICY ON INTELLECTUAL PROPERTY ,2013 AND THE INTELLECTUAL PROPERTY CONSULTATIVE FRAMEWORK, 2016

1. INTRODUCTION

Following some of the strides which have been made by other developing countries, in particular India in amending legislation on patent law so as to align itself with the TRIPS Agreement provisions, South Africa through the Department of Trade and Industry (DTI) issued an invitation through general notice in the Government Gazette calling upon for public comment on the National Policy on Intellectual Property.⁷² This was followed by the Government of South Africa's Intellectual Property Consultative Framework, 2016.

In this regard, Vawda remarks: "For South Africa, the decision handed down by the Indian Supreme Court in the *Novartis* case could not have come more timely. As South Africa's legislators and policy makers ponder a new draft Intellectual Property Law, they would take the import of this decision".⁷³ The two policy documents are discussed hereunder.

2. DRAFT NATIONAL POLICY ON INTELLECTUAL PROPERTY, 2013

The ultimate gazetting of the Draft National Policy was preceded by years of grappling with the issue culminating in the issuing of the Notice in the Gazette.

The policy framework document, which recognises the general need for an overhaul of the IP regime focuses on various issues which are covered in 17 chapters under the heading executive summary.⁷⁴

While there is an overlap on the policy framework document in that it focuses on the broader umbrella of the Intellectual Property regime, which include trademarks, copyrights, patents and designs, for the purposes of this contribution, the focus will be on patents.

⁷² Government Gazette no.36816, 4 September, 2013.

⁷³ Vawda Y After the Novartis Judgement 'Evergreening' will never be the same again. Law, Democracy and Development /Vol 18 (2014) at 305.

⁷⁴ Government Gazette no.36816, 4 September, 2013 at 3-4.

While issues relating to patents may be finding their way elsewhere in the chapters in the executive summary, special attention will be given to chapters 1,2 and 17 to the extent relevant.

In chapter 1, the Draft National Policy recognises the need for South Africa to create a substantive search and examination since it is using a depository system that inherently grant weak patents.⁷⁵ This weakness means that in the absence of innovation, given the fact that there are conclusive clinical trials for patents in the discipline of medicine, the absence of innovation will be inimical to access.

Importantly, the Draft National Policy Framework document, recognises flowing from the flexibilities of TRIPS, the need to recommend the change of the Patent Act to incorporate patent flexibilities as contained in the TRIPS Agreement after the Doha decisions and the general recommendation for the Patent Act to be amended to be amenable to issues related to Public Health.

These recommendations⁷⁶ are laudable and are fully in line with the recommendations and comments by the civil society coalition headed by the Treatment Action Campaign, Doctors Without Borders (MSF) and Section 27 who have been in vigorous campaign under the banner “Fix the Patent Laws”. The role of these organisations are dealt with in chapter six.

Other recommendations include discouraging bilateral agreements as the potential to stifle multilateral agreements and weakening the bargaining power in the international arena if you are caught up in them as a country.

The recommendation for the Patent Act to be amended to have a pre and post grant opposition to effectively foster the spirit of granting stronger patents is equally a notable recommendation. It is submitted that this will, following the Indian model, strengthen patent granting regime of South Africa which is generally accepted to be weak and susceptible to exploitation by the big pharmaceuticals and the country becoming a dumping ground for patent applications in the absence of a public scrutiny through the pre-and post opposition on the granting of a patent licence

In chapter 2, it is stated that the DTI industrial policy, 2007 noted that given the fact that developing countries do not have capacity of developing generic medicines and that a conscious decision should be taken as generic medicines do promote competition⁷⁷.

⁷⁵ Government Gazette no.36816, 4 September, 2013 at 8-9.

⁷⁶ See Government Gazette no. 36816 at 21.

⁷⁷ See Government Gazette no 36816, 2013 at 20 par 1.

This observation is supported by the recommendations of the country to facilitate legislation of making it easier to import drugs from other countries which may be offering a patented product cheaper through parallel importation process.

Further notable in chapter 2 dealing with IP and Public Health is the following provision

“There should be a balance between trade and health issues in relation to IP protection. During the Doha trade negotiations, access to public health and IP was high on the agenda. A major issue at Doha was how countries without capacities to manufacture medicine could procure under the realm of compulsory licencing⁷⁸”

The important issue is how do you strike the balance between trade and health issues? This is more so in that the Intellectual Property Consultative Framework document approved by cabinet on 6 July 2016, (which is discussed below) emphasises the protection of immaterial property right and cites S25 of the constitution and a Constitutional Court decision in this regard. On the one hand, there is recognition of Section 27, which manifestly accord the right to healthcare and services to everyone. The views of striking a delicate balance are being made in this contribution largely through the approach which could be followed by the courts either confronted by current legislations as they stand or the contemplated revamp through the amendments as currently proposed.

Finally, there is a list of recommendations which are made including: -

- The introduction of compulsory licencing in line with international treaties,
- Reconciliation of policy stances between the DTI and the Department of Health,
- Facilitation of legislation for introduction of parallel importation,
- IP, Competition and Trade Policies be in harmony with health policy objectives,
- IP protection regimes not contradict public health policies and balancing the two.

In one of the recommendations, it is expressly stated that South Africa should make provisions in its laws that will facilitate the entry of generic competitors as soon as the patent has expired on a particular medicine. The Bolar⁷⁹ provision is already in the Patents Amendment Act 2002.

The above means that some activism from Government through an amendment was made through Patents Amendment Act 2002, introducing the Bolar provisions. It is submitted that notwithstanding the amendment, the benefit from the amendment has not been adequately utilised, if at all.

⁷⁸ See Government Gazette notice no. 36816 at 20 par 3.

⁷⁹ See patents at amendment Act No. 58 of 2002 (section 69A).

3. THE GOVERNMENT OF SOUTH AFRICA'S INTELLECTUAL PROPERTY CONSULTATIVE FRAMEWORK, 2016

A snapshot of the Intellectual Property Consultative Framework document in particular dealing with Patent Law and access to health will be analysed and critiqued hereunder.

The Cabinet approved an Intellectual Property Consultative Framework on 6 July 2016.

1. The Government Consultative Framework recognises the argument of the Pharmaceutical Companies relating to the Constitutional right to property as envisaged in the constitution to be inclusive of the immaterial property right of intellectual property i.e. a patent right.

Under the heading, Purpose, the document expressly provides (vii) “The South African Constitution guarantees the right to property and that no law may permit arbitrary deprivation of property.⁸⁰ “

2. It goes further to state: In terms of the Constitution, property is not limited to land and would by implication include IP. It then quotes the *Re: Certification of the Constitution of the RSA*.⁸¹ It further provides that the Constitution provides a balanced approach to property rights by also taking into account public interest. In this regard public interest includes the countries' commitment to bring about reforms of the IP policy in line with the Constitution.
3. What is striking is that much as the promotion of public health is listed as one of the objectives which the IP policy should advance and issues which need immediate domestic review under the heading 4 (immediate issues include among others parallel importation, compulsory licences, IP and competition Law), the constitutional right of access to health has lost an opportunity of being clearly spelled out especially as South Africa having played a significant role in promoting and advancing the rights of Governments of developing countries to bring to the attention of the countries of the world that the IP rights should not be promoted in a manner which will have a detrimental effect of defeating the rights of access to health and medicine for the majority of the citizens. It is similarly noted that in the course of advancing the objectives, the IP Policy will be cognisant of both the international, regional and domestic context by amongst other things: -
 - (a) engendering the ethos of the Constitution,
 - (c) develop a co-ordinated intergovernmental approach to IP

⁸⁰ See Section 25 of the Constitution of the Republic.

⁸¹ 1996 (4) SA 744(CC) and *Laugh it off Promotions CC v South African Breweries International (Finance)*.

- (d) strike a balance between creators and users of IP,
- (h) adopt a co-ordinated approach to IP in sub-regional, regional and international forums, and
- (i) promote Public Health.

The document however does not show some sense of appreciation of the need to urgently effect reform in key areas while at the same time appreciating the fact that there is a need to tread carefully and guard against using urgency when there is a need to sufficiently deal with highly technical, important and contentious issues with requisite depth and analysis.

It consequently suggests that immediate issues be dealt with timelines attached to them.

Whatever falls within the medium-term issues which are expected to be done in accordance with international best practices such as WIPO methodologies would require more flexible timelines.

Lastly, the monitoring and evaluation would be undertaken with a view of undertaking impact assessment and alignment with the broader IP Policy where necessary, with flexible timelines. Countries from least developed nations were given until the end of 2016 to comply with TRIPS provisions of ensuring that patents and rights thereto are protected. It is therefore submitted that to start an engagement of the monitoring and evaluation committee to undertake an impact study in 2016 demonstrate the lack of political commitment in the midst of the need to treat the matter with a sense of urgency as has been advocated by lobby groups for a number of years. It demonstrates complacency in addressing a thorny issue.

This submission is made mindful of the fact that there are certain provisions of TRIPS which the current Patent Laws are compliant with.

There remains a lot of patent provisions which the SA Legislation still does comply with. The majority of them are part of the proposed amendments for legislative reforms.

Above all, the Government Gazette on Intellectual property reform, 2013 and the subsequent consultative documents of 2016 move from the understanding of the need for an overhaul of IP laws to align among others with TRIPS provisions.

A complicating factor is the recent request by the least developed Countries to extend the compliance period beyond 2016. This request was acceded to by the TRIPS council extending the transition period until 1 January 2033 or when such country ceases to be a least developed country if that happens before 1 January 2033.⁸²

⁸² WTO IP/C/73, 6 November 2015.

Under the heading strategy, it is important to note the express provisions of 2(VI) which reads:-

“It is proposed therefore that in light of the urgency, importance, high public profile as well as strong institutional capacity and experience possessed by Government on the intersection between IP and Public Health which covers among other medicines, vaccines and diagnostics, this area together with its multiplicity of sub-issues should be immediate priority. It is also important to pursue areas where South Africa has international commitments such a geographic indication to comply with and take advantage of opportunities contained in international agreements”.

While one may not confirm the strong institutional capacity and experience possessed by government on intersection between IP and Public Health, it is worthy to note the prioritisation of IP and Public Health and the need to deal with this aspect urgently. If the discussion were to translate to action, given the lost opportunity of working on taking advantage of the provisions of the TRIPS Agreement in promoting access to health care, this would assist to ameliorate the position of the vulnerable citizens who cannot afford medicine due to the pricy costs.

The IP Consultative Framework recognises S25 of the Constitution, the very argument which was used in *PMA & others v President of the RSA & others* dealt with in chapter four, (a case in which TAC was admitted as amicus curiae) and applicants subsequently withdrew. This point raises a profound argument which had been aptly dealt with by Yousuf A Vawda and Brooke Baker.⁸³

While it is correct that the *Certification case and the Laugh it off Promotions CC cases* affirmed the immaterial property right under Section 25 of the Constitution, the reality of taking the delicate balance of S25 and S27 taking into account principle 1 and 2 of the Global Compact. The need to amend IP laws, in particular Patent Laws to deal with the need to promote access to health is an important one and the question as to which right should trump another under the circumstances becomes very important.

Vawda remarks as follows in his article

“Indian legislators exploited the latitude or flexibility allowed in the Agreement to exercise their freedom to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice. “⁸⁴

While India exploited the gap as it did, it is submitted that given the opportunity which it has, South Africa can achieve the same result as India, but using a different approach to the one

⁸³ Vawda A and Baker B Achieving Social Justice in the Human Rights/ Intellectual Property Debate: Realising the goals of access to Medicine African Human Rights Journal (2013) 13 AHRJ 55 -81.

⁸⁴ Page 2 par 2.

adopted by India. As South Africa is equally bound by TRIPS agreement, it has an opportunity to align itself with the provisions of the TRIPS Agreement consequently fulfilling the Principles 1 and 2 of the “Global Compact” announced by the UN Secretary – General Kofi Annan in January 1999. Having been tried and tested, there is nothing which stops South Africa from taking cue from how India did it in *toto* given the advantage for IP reform it is sitting on.

It is further submitted that South Africa with its various legislative framework can still achieve the same result as was done in India through Section 15C of the Medicines and related Substances Act 101 of 1965. This section is mentioned in chapter two and dealt with in chapter four.

The Court interpretation of a relevant legislation can equally play an important role in ensuring that the constitutional imperatives are equally met. The views of Vawda regarding the role courts are equally valid as one of the many ways of approaching evergreening in South Africa especially having regard to the prevalence of HIV/AIDS and the benefit which would be derived from such approach is through bold pronouncements by courts.

While there are so far, no ground-breaking judgements through the lobby groups, the Competition Commission and the Constitutional court have demonstrated their respective role in asserting and interpreting the Constitutional human rights impacting on access to medicine. The relevant cases to support the submission are dealt with in chapter four and the role of lobby groups is equally acknowledged in the same chapter as well as chapter six.

While other countries are using the legislative framework to exploit the loopholes which arise out of the TRIPS Agreement for the benefit of their citizens, as Indian courts have through judgements on compulsory licencing and “evergreening”, South Africa has comparatively remained slow in dealing with the issue of promoting access to medicines for the poor through patent law. The failure of South Africa has been very conspicuous in it not effectively dealing with the benefits to developing countries arising out of the Doha declaration. The amending of the Patents Act and other IP Laws for alignment with TRIPS agreement and the introduction of national legislative provisions in line with the TRIPS provisions coupled with the strengthening of the Patent Act to protect citizens remains the proper route for the country to follow.

The South African Patent Act 57 has got identifiable gaps which have made it to be very prone and susceptible to exploitation by multinational pharmaceuticals, chief among which is the patent registering system.

While making these criticisms, one is mindful of the role of the South African Government and activist organisations in the *PMA* case, which was an eye opener contributing to the adoption

of the Doha Declaration in 2001. The amendments and introduction of Section 15C of the Medical Control and Substance Act was a laudable initiative which should not be taken lightly.

The same goes for the settlement agreement between *Hazel Tau and Others v Glaxosmith, Boehringer Ingelheim* and *Hazel Tau & Others v Boehringer Ingelheim* which were facilitated by the Competition Commission.

4. CONCLUSION

Despite the delays in implementing the changes in IP laws and the disastrous consequences of complacency, a substantial portion of the concerns raised and submissions made by the civil society coalition groups and various commentators have largely been taken into account in developing the consultative framework document. This is an exciting prospect for the future of access to health care from the perspective of patents and human rights. It does inspire confidence to the ideals of the Global Compact as spelled out in Principles 1 and 2 thereof.

CHAPTER SIX

THE ROLE OF CIVIL SOCIETY GROUPS IN PROMOTING ACCESS TO HEALTHCARE.

1. INTRODUCTION

The failure by South African Government to fast track amendments to legislation on patent law, for the benefit of its citizens amid fierce and vociferous opposition to change in the current IP regime was leaked in the “Pharmagate⁸⁵”. Civil society and activist’s groups in particular TAC has led the charge in exposing this scandal amongst others. In India the cases discussed in chapter three involved civil society groups playing a central role in asserting the rights of the citizens to access affordable medical healthcare.

As one of the identified gaps, the provisions of the Patents Act dealing with examinations of applications and specifications state: ⁸⁶“The registrar shall examine in the prescribed manner every application for a patent and every complete specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of the Act, he shall accept it.”

The DTI has not taken steps to implement the provision. South Africa does not examine patent application to see if they meet national criteria for what deserves a patent.

The civil society coalition including but not limited to Treatment Action Campaign (TAC), Doctors without Borders (MSF), Aids Law Project and Section 27 continuously engage with DTI and publicly pronounce on the need for the Department to attend to the identified gaps within the patent laws which have the catastrophic effect of hindering access to medicine or drugs to the majority of the population in need. The Government itself as the provider of free drugs would stand to benefit out of expediting the amendments to the Patent Act.

Below are some of the proposed reforms as identified by the civil society coalition, which I agree with. The fact that it would assist the country to move from a patent registration system to a patent examination system, with checks and balances through greater transparency from the patent offices and allowing third parties to do patent opposition. This is one of the methods

⁸⁵ The name of the Scandal in which the US and European pharmaceutical industry including Abbott Laboratories SA, Abbie, Bristol Myers Squibb, Eli Lilly SA, MSD and Pfizer sought to delay South African IP reform by financing a covert US\$ 600,000 Campaign.

⁸⁶ Section 34 of the Patents Act

which are applicable in the Indian Patent Law and are scrupulously scrutinised and adhered to.

As one of the developing countries which stand to benefit from the Doha declaration, the identified weakness of being prone to abuse by international pharmaceutical companies has not escaped South Africa through the process of “evergreening”. This matter the central topic in their contribution.

Lessons from India, regarding stricter national criteria should be adopted to avoid “evergreening”. It should be noted that due to this identified gap, the abuse of the process of evergreening is going on unabated. In the absence of stringent legislation, which aligns itself with the already tested provisions of the TRIPS Agreement, as already legislated and applied by Courts of Law, in India, the exploitation through excessive prices and the continued vulnerability of the majority in South Africa and other developing and least developed countries will continue.

One of the methods of unlocking the opportunity of access to healthcare while still in compliance with the TRIPS Agreement is using compulsory licences system. The concept of compulsory licencing has its genesis from the early ages and has been practised in various countries e.g. it has been prevalent in the 1830's and first used in Britain in the 1850's.⁸⁷

However, as Vawda and other commentators, including the lobby group correctly point out that to date South Africa has not issued a single compulsory licence on medicine. This is attributed to the cumbersome process which is followed when one needs to obtain the licence. This can equally be answered by the legislative reform and navigating the provisions within the prescripts of TRIPS to achieve an objective which is open to be utilised.

Like India, South Africa should adopt at least easier processes for issuing of compulsory licences. This will give an opportunity to courts and tribunals to be arbiters after the licence had been issued by the established competent authority than is currently the case.

The use of parallel importation is something which should equally be looked at as the country is failing in this regard. Through parallel importation, the use of medicines which are imported from other countries at a lower price comparatively would be very beneficial to the country's citizens.

⁸⁷ Raju K The First Compulsory Licencing case in India under the TRIPS Agreement: An analysis of Bayer versus Natco Pharma Ltd, *Journal of Development Policy and Practice* at page 72.

Another problem which has been identified is that when medicines are patented multiple times, it has an enormous potential of hindering research and development of improved follow on products, such as combination therapies, or paediatric formulation of medicines.

The Coalition group proffers a view that the country could adopt a broad research and educational use exception to patent rights. They further argue that if this is allowed, it means that if a researcher or generic manufacturer wants to work with a patented product to improve upon it in some way, that research does not constitute a patent infringement.

The writer concurs with the above highlighted gaps, limitations and recommendations as identified by the civil society groups and presented to DTI as submissions. They constitute proposed reforms which would go some way in promoting access to healthcare which the identified groups continue to grapple with in their endeavours of making the world a better place to be even for the needy and downtrodden particularly and not limited to developing countries.

Equally, there are people in developed nations who would derive a benefit from the robust engagement which culminated in the Doha declaration and consequently found itself in the TRIPS Agreement. It can be strenuously argued that the general duty of access to healthcare should not necessarily be limited to developing countries. This is a right which should accrue to everyone regardless of the fact that you are based in a developed country. As a citizen and a human being, depending on your country's healthcare system, if you cannot afford the medicines as a result of strict Patent Laws to which your country has subscribed to as it does not form part of the list of less developed countries, there should be a case for you based on affordability. This is relevant in particular to developed countries which do not offer a full public health system for their citizens.

The developments subsequent to the release of Draft National Policy on Intellectual Property (IP) of South Africa, issued under General Notice 918 of 2013, can be described as having been slow for the liking of the generally affected masses and in particular to those who are spearheading the lobby groups e.g. section 27, Treatment Action Campaign, Doctors Without Borders and multiple signatories to the "fix patent law". However, almost all the recommendations as proposed by the civil society coalition are covered in the intellectual property framework document, 2016.

In *Cipla Medpro (Pty) v Aventis Pharma SA, Aventis Pharma SA & Others v Cipla Life Sciences (Pty) Ltd & Others* wherein the TAC represented by section 27 in the SCA a question of South African Courts' commitment to interpreting the Patents Act was put to question.

In his article after the *Novartis* judgement, evergreening will never be the same, Vawda opines that the South African judiciary could take leaf from the Indian Supreme Court, which when the circumstances so dictated did not shy away from considering public policy arguments in interpreting and applying patent law. He draws a stark contrast from the failure of the Supreme court of Appeal in the case of *Cipla Medpro (Pty) Ltd v Aventis Pharma SA, Aventis Pharma SA and Others v Cipla Life Sciences (Pty) Ltd and Others*.⁸⁸

The relevance of this case is among other reasons: -

1. It deals with Patent Law, in particular – a secondary patent resulting in the extension of its original lifespan of 20 years, thus importing the cried about notion of evergreening which is afflicting the poor in a strenuously negative way in South Africa insofar as it affects them in addressing drugs at a lesser price than the original patented drugs.
2. An opportunity which merited consideration presented itself. As he puts it “While essentially a dispute about whether a pharmaceutical patent can obtain an interdict against an alleged infringer, this was a significant test case for the extent to which Courts are required to apply broad constitutional principles in this case the right to access to healthcare services and medicines in IP disputes”.⁸⁹
3. A lobby group TAC made an application to court to be admitted as an *amicus curiae*. Noting the role of an *amicus curiae* in court, the question is whether you can through your submissions make inputs that can cause the court to make a binding principle on a ground-breaking decision which may affect the litigants. Perhaps government or TAC could should have joined as an intervening party and not in as an *amicus curiae*?
4. The finding of the Court in that matter in relation to future cases of a similar nature will be discussed. The subsequent Supreme Court of Appeal in *Pharma Dynamics v Pharma AG & Bayer Pharma Ltd*⁹⁰ which came after the *Cipla* case, did it inspire hope for such foreseeable intervention by our courts? Should Patents Commissioners who sit as judges *a quo* be alive to the constitutional values underpinning the need for the application of constitutional rights and to the extent relevant infuse those rights in their judgement so as to give an opportunity to the Supreme Court of Appeal to also deal with the Constitutional ethos and values?

⁸⁸ 2013(3) SA 579 (SCA).

⁸⁹ See page 316 par 1.

This question is very important bearing in mind that a Presiding Officer in a patent matter sits as a Commissioner *a quo* and when an appeal or review is done, it come straight to the Supreme Court of Appeal.

2. CONCLUSION

It is submitted that lobby groups and associations should continue to play a central role in asserting citizens' rights of access to medicine. The role played by civil society groups e.g. TAC, COSATU and section 27 cannot be underemphasised. They continue to be in the driving seat in asserting the right of access to healthcare. They have demonstrated this commitment through landmark cases, protests, picketing and making submissions to role players like the cabinet and international bodies like the UN and the WHO. The cases which are being discussed in this contribution including *PMA & Others, President of the Republic of South Africa and Others, TAC v Minister of Health and Others, Cipla Case, Hazel Tau & Others* are but some of the examples which bear testimony to the fundamental role of civil society organisations in fighting for the needy. Interestingly, they wage their challenges not only against big pharmaceuticals but equally go against Government in the event of recalcitrance on its part.

It can be argued that our domestic pharmaceutical companies do not have an appetite to assert the right largely for their role as generic medicine manufactures to assist the citizens with cheaper drugs by among other initiatives arguing against evergreening through licence applications while legislative reform is pending.

CHAPTER SEVEN

REFLECTIONS, CONCLUSIONS AND RECOMMENDATIONS

1. REFLECTIONS AND CONCLUSIONS

The global issue relating to multinational pharmaceutical companies and evergreening continues to be one of the biggest bones of contention within the health fraternity affecting developing and underdeveloped nations. The entering onto the fray by the UN through the Global Compact advocating the need for business, institutions and nations around the World not to be complicit to issues of human rights while in the course of conducting their businesses could not have come at a better time following the continuing debates of the TRIPS Agreement arising out of the Doha Declaration.

South Africa, as a developing nation is equally confronted by the issue of access to health and has through its fragmented legislations strived to contribute to this issue which is affecting the majority of the population due to the health system in the country and the affordability due to the prices which remain astronomically high consequent to evergreening which results in a barrier of access to cheaper and affordable generic medicines.

2. RECOMMENDATIONS

Throughout various chapters, there are reflections on how patent laws affect access to affordable drugs and medicines and recommendations on how role players may assist in achieving the constitutional objective of access to healthcare as enshrined in Section 27 of the Constitution. To this end and considering to other recommendations in various chapters, the following recommendations, although non-exhaustive are made: -

1. It is recommended that the process of amendments to the weak and fragmented IP regime to be expedited as it has taken long to address and the negative effects of evergreening continue unabated.
2. The harmonisation of pieces of legislations relevant for IP and health laws must be explored and attended to.

3. While civil society groups have been, playing a significant role in promoting the right of access to affordable medicines, it is recommended that they maintain their vigilance both within and outside their jurisdictions. In solidarity with the civil society groups of other nations, their continued quest for a better life for their citizens will remain in the map and progressive realisation will be achieved.
4. Individuals, civil Society and any other public interest groups should also identify IP cases, heard by the patent commissioner and if identified as relevant raise constitutional issues at that stage following successful admission as intervening parties preferably as opposed to *amicus curiae*.

After considering to all the reflections, conclusions and recommendations the highly acclaimed and famously made quotation by the then Prime Minister of India as captured in chapter one is and should remain an ideal to strive for.

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ABBREVIATIONS

CAC	Competition Appeal Court
CC	Constitutional Court
CL	Compulsory Licencing
COSATU	Congress for South African Trade Unions
DTI	Department of Trade and Industry
EU	European Union
FTAA	Free Trade of Americas
HIV AIDS	Acquired Immune Deficiency Syndrome
IFPMA	International Federation of Pharmaceutical Manufactures Associations
ILO	International Labour Organisation
IMF	International Monetary Fund
IP	Intellectual Property
IPAB	Intellectual Property Appellate Board
IPR	Intellectual Property Rights
MSF	Doctors Without Borders
NDHR	United Declaration of Human Rights
NDP	National Development Plan
PMA	Pharmaceuticals Manufactures Association
R&D	Research and Development
RSA	Republic of South Africa
SA	South Africa
SCA	Supreme Court of Appeal
SAMJ	South African Medical Journal
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNDP	United Nations Development Programme
UNESCO	The United Nations Educational, Scientific and Cultural Organisation
USA	United States of America
WEF	World Economic Forum
WIPO	World Intellectual Property Organisation
WHO	World Health Organisation
WTO	World Trade Organization