**CML 6006W MASTERS IN COMMERCIAL LAW**

DISSERTATION TITLE:

# THE FORMULATION AND IMPLEMENTATION OF COMPETITION LAW AND POLICY AND HOW IT WILL ADVANCE THE DEVELOPMENT OBJECTIVES OF A DEVELOPING COUNTRY:

## THE CASE OF PUBLIC HEALTH IN THE REPUBLIC OF BOTSWANA


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Research dissertation presented for the approval of Senate in fulfilment of part of the requirements for the Masters in Commercial Law degree in approved courses and a minor dissertation. The other part of the requirement for this qualification was the completion of a programme of courses.

I hereby declare that I have read and understood the regulations governing the submission of Masters in Commercial Law degree dissertations, including those relating to length and plagiarism, as contained in the rules of this University, and that this dissertation conforms to those regulations.

Signature: Date:

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## INTRODUCTION

### *Brief History*

The Republic of Botswana was formerly the British Protectorate of Bechuanaland and subsequently adopted its present name upon independence in 1966. The country has had four decades of uninterrupted civilian leadership, progressive social policies, and significant capital investment creating one of the most dynamic economies in Africa. Mineral extraction, principally diamond mining, dominates economic activity, though the tourism sector is growing in leaps and bounds possibly due to the country's conservation practices and extensive nature preserves. By the end of 2003, Botswana had the world's highest known rate of HIV/AIDS infection but also one of Africa's most progressive and comprehensive programs for dealing with the disease.[1]

### *Geography*

Botswana is located in the southern part of Africa just to the immediate north of South Africa. Botswana is a land-locked country of area six hundred thousand three hundred and seventy square kilometers (600 370 sq km). The landscape is made up of predominantly flat to gently rolling tableland, with the Kalahari Desert in the southwest. The climate is semi-arid with warm winters and hot summers.

Amongst the natural resources that can be found in Botswana are diamonds, copper, nickel, salt, soda ash, potash, coal, iron ore, and silver. Up until the year 2005 it was established that land use in Botswana was split as follows: 0.65 *per cent* was Arable land;

0.01 *per cent* was permanent crops; and

99.34 *per cent* was for others.[2]

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[1] The facts and figures on the Republic of Botswana are available on the website of the US Central Intelligence Agency at www.cia.gov/cia/publications/factbook/geos/index.html

[2] *Ibid* note 1

***People***

As at July 2006 the US Central Intelligence Agency (CIA) had established that Botswana had a population of one million six hundred and thirty-nine thousand eight hundred and thirty-three (1 639 833). In making these estimates, the CIA took into account excess mortality due to AIDS which in turn can result in lower life expectancy, higher infant mortality and death rates, lower population and growth rates, and changes in the distribution of population by age and sex than would be otherwise expected.[3] The CIA figures indicate that the prevalence of HIV/AIDS amongst adults was 37.3 *per cent* in 2003, and the number of people living with the disease is shown as three hundred and fifty thousand (350 000). In a recent interview with a local newspaper, the president of Botswana, Festus Mogae, stated that the overall prevalence rate in Botswana is about 17.1 *per cent* as opposed to the 33 *per cent* reported by the UNAIDS organization.[4] He sought to justify this by citing that the disparity in the prevalence between different age cohorts, and gave as an example, the fact in the 15 to 24 age cohort, the prevalence rate is about 10 *per cent*. But notwithstanding this, the President does acknowledge that Botswana is seriously affected by the disease and that it should take measures to fight the pandemic.

***Economy***

According to the CIA, Botswana has maintained one of the highest growth rates since independence in 1966 and, through fiscal discipline and sound management, Botswana has transformed itself from one of the poorest countries in the world to a middle-income country with per capita GDP of $10 000 in 2005. The CIA states, further, that two major investment services rank Botswana as the best credit risk in Africa. Diamond mining has fueled much of the expansion and currently accounts for more than one-third of GDP and

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[3] *Ibid* see note 1

[4] The Mmegi Newspaper, Vol.23 No.158 of 20 October 2006 reported the President as having said the following:

> 'The figures used by the UN were based on sample surveys on expectant women, who were not adequately representative…. And the correct national prevalence rate is about 17.1 *per cent*.'

for between 70 and 80 *per cent* of export earnings. Tourism, financial services, subsistence farming, and cattle rearing are other key sectors.[5]

On the downside, the government must deal with high rates of unemployment and poverty. The CIA avers that unemployment is officially stated as 23.8 *per cent*, but unofficial estimates place it closer to 40 *per cent*. The CIA avers, further, that HIV/AIDS infection rates are the second highest in the world and threaten Botswana's impressive economic gains, and that long-term prospects are overshadowed by the prospects of a leveling off in diamond mining production. The currency of the Republic of Botswana is Pula (BWP) which exchange rates over the past few years have indicated the number of Pulas per US dollar as: 5.1104 in 2005; 4.6929 in 2004; 4.9499 in 2003; 6.3278 in 2002; and 5.8412 in 2001.[6]

The following are some of the pertinent economic data, in figures, as extrapolated from the CIA *website supra*:

| **Economic Trends** | **Value** |
|---|---|
| GDP purchasing power parity | $17.53 billion (2005 est.) |
| GDP real growth rate | 5.5 *per cent* (2005 est.) |
| GDP per capita purchasing power parity | $10 700 (2005 est.) |

[5] *Ibid* see note 1
[6] *Ibid* see note 1

| GDP composition by Sector | Value |
|---|---|
| Agriculture<br>Industry<br><br>Services | 2.4 *per cent*<br>46.9 *per cent* (including 36% mining)<br>50.7 *per cent* (2003 est.) |

| Socio-economic Indicators | Percentages |
|---|---|
| Population below poverty line | 30.3 *per cent* |
| Inflation rate (consumer prices) | 8.6 *per cent*<br>(2005 est.) |
| Unemployment rate | 40 *per cent*<br>(the official rate is 23.8%)<br>(2004 est.) |
| Industrial production growth rate | 7.5 *per cent*<br>(2005 est.) |

| **Trading Patterns** | **Value** |
|---|---|
| Exports | $3.68 billion f.o.b. (2005 est.) |
| Exports – commodities:<br>Diamonds<br>Copper, nickel, soda<br>ash, meat, textiles | |
| Exports – partners:<br>European Free Trade Association (EFTA)<br>Sothern African Customs Union (SACU)<br>Zimbabwe | <br>87 *per cent*<br>7 *per cent*<br>4 *per cent* (2004) |

| **Trading Patterns** | **Value** |
|---|---|
| Imports<br><br>Imports – commodities:<br>foodstuffs,<br>machinery, electrical goods, transport<br>equipment, textiles, fuel and petroleum<br>products, wood and paper products, metal and<br>metal products | $3.37 billion f.o.b. (2005 est.) |
| Imports – partners:<br>Southern African Customs Union (SACU)<br>EFTA<br>Zimbabwe | <br>74 *per cent*<br><br>17 *per cent*<br>4 *per cent*<br>(2004 est.) |
| Debt – external | $519 million<br>(2005 est.) |
| Economic aid – recipient | $73 million<br>(1995) |

***Health***

The health statistics presented herein were sourced from the Central Statistics Office website.[7]

As of the year 2003, the number of health facilities in the country were as follows:

| | |
|---|---|
| Clinics | 257 |
| health posts | 336 |
| mobile stops | 761 |

As of the year 2003 the ratios of medical personnel per 10 000 people in Botswana were as follows:

| | |
|---|---|
| Doctors | 3.1 |
| Nurses | 26.1 |

The Ministry of Health maintains a disease surveillance system aimed at effectively monitoring and controlling outbreaks and spread of diseases of epidemic and contagious nature. The five most significant diseases derived from this system are malaria (confirmed), measles, rabbies (exposure), viral hepatitis, and diarrhoea.

Statistics show that in the year 2003, ninety-eight thousand four hundred and fifty-two (98 452) discharges and ten thousand and sixty-two (10 062) deaths were recorded. The leading cause of morbidity registering 8 *per cent* of all causes was AIDS, while the leading cause of mortality was also AIDS, accounting for 26.7 *per cent* of all deaths.

[7] www.cso.gov.bw

From the above health statistics, it is evident that Botswana has a very serious public health problem. This being so as there is a shortage of medical personnel (doctors and nurses), which problem is also magnified by the exodus of nurses to the United Kingdom, and in terms of the percentage of patients that are dying from the HIV/AIDS pandemic. This pandemic will, in the not too distant future, have the effect of greatly reducing the life expectancy of the country which in turn will have a negative impact on the economy of the country as this would mean a loss of productive manpower due to the pandemic and therefore reduced productivity in all sectors of the economy.

At present, the government of the Republic of Botswana has been carrying out an exercise of providing anti-retroviral medicines to people suffering from HIV/AIDS. This much is evident from the 2006 Budget Speech that was delivered to the National Assembly by the Minister of Finance and Development Planning, Honourable Baledzi Gaolathe when he said the following:

> 'Mr Speaker, the African Comprehensive HIV/AIDS Partnership (ACHAP), which is a collaboration between the Government of Botswana, Bill and Melinda Gates Foundation [sic] and Merck Foundation, has extended its programme of assistance to Botswana to 2009. In addition, the Merck Foundation has agreed to extend donation of their two antiretroviral drugs to the Government of Botswana to 2009, and Boehringer-Ingelheim's partnership with Government continues to train personnel engaged in the war on AIDS. The Global Fund to Fight AIDS, Tuberculosis and Malaria started implementation [sic] of its activities in Botswana during 2004 under a grant agreement worth about US$18.6 million or about BWP100 million to cover assistance to the Non-Governmental Organisations/Community Based Organisations [sic], and

the roll-out of the Prevention of Mother to Child Transmission Programme [sic].'[8]

It should be noted that these anti-retroviral drugs are very costly to acquire (despite the subsidies and donations) and as such it would not be economically sustainable for the government to continue with the program in the long run. Some of the unpublished figures that I managed to get from the outgoing head of the MASA government ARV roll-out program only serve to buttress this point.[9] In agreeing with the statement made by President Mogae in his recent interview,[10] Ramotlhwa says that there are currently sixty-four thousand (64 000) patients under the government anti-retroviral therapy (ART) program and an additional estimated eight thousand seven hundred (8700) patients on ART in the private sector. The former government official says that, on average, the cost per patient per annum is about five thousand Pula (BWP5000), and this cost is inclusive of drugs, laboratory tests, human resource, infrastructure, monitoring, evaluation, etc.

Ramotlhwa avers, further, that ACHAP (the Bill & Melinda Gates Foundation and Mreck Company Foundation) has contributed less than 10 *per cent* of the total cost of the roll-out program, and that the cumulative support from all partners since the year 2001 was less than 15 *per cent* as at May 2006 when he cut his ties with the program. All in all, this serves to show that government is carrying the heaviest burden in its fight against AIDS, which, in the long run, will make it not to be sustainable and economically feasible for it to continue with the roll-out program.

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[8] Budget Speech delivered on the 6th February 2006, available from the Government website www.gov.bw/docs/BudgetSpeech2006.pdf, at para 55 on page 13

[9] Mr Segolame Ramotlhwa contributed immensely in the conceptualization of the MASA ARV roll-out program. He was involved in the projections for the infrastructure, staffing, and costs of the program. He is the recent recipient of the 2006 German Africa Award from the German Africa Foundation, in recognition of his efforts in fighting HIV/AIDS to secure peace and health for future generations in Botswana.

[10] *Ibid* see note 4

The diversion of public funds towards the fight against HIV/AIDS will also disrupt development in that other sectors of the economy would be by-passed so that the fight against the pandemic can be funded. At this juncture, this is where the negotiations in the World Trade Organization (WTO) become of great consequence to the Republic of Botswana. This is especially because it is through negotiations in the WTO that Botswana can bargain for favorable conditions in the area of public health with regard to the prices of medicines for diseases which afflict her, for example, HIV/AIDS, malaria, tuberculosis *et al*. As such, the Doha Declaration[11] was thought to be of great importance to the Republic of Botswana and other developing countries. Legal commentators believe that the Declaration arose as a result of pressure being exerted by African countries on the Council on TRIPs[12] before the fourth ministerial conference of the WTO.[13]

[11] See the DOHA WTO MINISTERIAL Declaration on the TRIPS Agreement and Public Health WT/MIN(01) 20 November 2001, available from the World Trade Organization website at www.wto.org/english/thewto_e/min01/mindecl_trips_e.htm

[12] The World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights

[13] See A O Adede, Streamlining Africa's Responses to the Impact of the TRIPs Agreement, ICTSD, International Environment House 13 chemin des Anemones, 1219 Geneva, Switzerland. Available at www.ictsd.org/pubs/ictsd_series/iprs/ADEDE_2001_English.pdf

# CHAPTER ONE

## THE WTO MULTILATERAL TRADING SYSTEM AND ACCESS TO MEDICINES

### (i) *The DOHA Declaration on the TRIPS Agreement and Public Health*

After constant lobbying by the African group arguing that contrary to the principles and objectives of the TRIPs agreement, the then present model on intellectual property rights protection was too heavily tilted in favor of right holders and against public interest, the African group proposed that there be convened a Special Session of the TRIPs Council to address the issues relating to the TRIPs agreement, patents, and access to medicines. Adede, in his writing,[14] says that an allowance for the flexible interpretation of article 31 of the TRIPS agreement[15] would permit African governments to enact appropriate national legislation enabling their people to have access to affordable generic aids drugs through 'compulsory licensing' or 'parallel importing'. Such an interpretation, the author reasons, would be applied in a supportive manner while still retaining its characteristic of being a viable legal vehicle for protecting the interests of patent owners.

Adede avers that from all this lobbying was born the Doha Declaration *supra* which some commentators believe had no legal effect but to interpret what was already contained in the TRIPs agreement. However, the author maintains that the Doha Declaration had the effect of finally recognizing [in an explicit manner] the gravity of the public health crises affecting many developing and least-developed countries, particularly with regard to the crises emanating from HIV/AIDS, tuberculosis, malaria, etc.

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[14] *Ibid* see note 13, at page 15

[15] Article 31 provides for the use of the subject-matter of a patent without the right holder's authorization, including use by the government or third parties authorized by the government. This though, only where the national law of the member state permits such compulsory licensing

At paragraph 4 of the Declaration, the Ministers agreed that the TRIPS Agreement should be interpreted in a flexible and supportive manner by saying the following:

> '[w]e agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. [My emphasis]
>
> In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.'[16]

Adede underscores, further, that moreover, the Declaration explicitly affirmed that HIV/AIDS, tuberculosis, malaria and other epidemics 'can represent a national emergency or other circumstance of extreme urgency, as may be determined by a member state of the WTO, thus triggering the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted'. This will then enable the state concerned to have access to generic versions of patented drugs which are more affordable.[17]

The commentator is of the view that by confining itself to compulsory licensing, the Declaration has arguably excluded most African countries from its benefits since they do not have local capacity to make use of compulsory licensing, unlike say, the bigger developing countries such as India, South Africa, and Brazil which all have significant local drug manufacturing industries. This is particularly true for Botswana as she has been unable to use the flexibilities of the TRIPs agreement to manufacture generic drugs for the sole reason of a lack of the necessary capacity. Adede felt, then, that the so-called 'breakthrough' facilitated by the emergence of the Declaration was

[16] *Ibid* see note 11
[17] *Ibid* see note 11, at para 5

somewhat exaggerated. Nonetheless, he did acknowledge that the Declaration did prepare the ground for further actions on the matter. Here, he quotes the Declaration where it states the following:

> 'We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.'[18]

As a result of this recognition and acceptance of the problem facing developing such as Botswana *vis-à-vis* capacity constraints, the WTO made a follow-up by passing the decision attempting to resolve the dilemma presented by paragraph 6 of the Declaration as alluded to herein.

As a parting shot, on the access to drugs problem, Adede made a few recommendations or suggestion of what he thought African policymakers and negotiators at the TRIPS Council should push for. Amongst his suggestions was that African countries should endeavour to:

> '… introduce appropriate national legislation to enable African countries to take advantage of compulsory licensing or parallel importing, including laws against restrictive trade practices in this area (antitrust laws) that would together permit the interpretation and application of the TRIPS Agreement in a genuinely flexible and supportive manner as recognized by the Doha Declaration.'[19]

Here, the author was thinking very much ahead of time, and this is backed by the fact that it is only now that Botswana and other developing countries see the need to enact antitrust laws. However, I do not wish to dwell on this point as the topic will be dealt with in my next chapter.

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[18] *Ibid* see note 11, at para 6
[19] *Ibid* see note 13, at page 16

### (ii) *Implementation of Paragraph 6 of the Doha Declaration*

As a follow-up to the Doha Declaration, and pursuant to the directive therein instructing the Council for TRIPS to 'find an expeditious solution to this problem [of paragraph 6 of the Declaration relating to lack of capacity by developing countries] and to report to the General Council …,'[20] the August 2003 Decision was drafted.[21] The Decision noted that exceptional circumstances existed so as to justify waivers from the obligations[22] set out in paragraphs (f) and (h) of the TRIPS Agreement[23] with respect to pharmaceutical products. In this way, developing countries with manufacturing capacity in the pharmaceutical sector, such as India, South Africa, and Brazil, would be able to export generic aids drugs to those with no manufacturing capacity such as Botswana. This would make for cheaper drugs to be available since competition from generic drugs has been shown to have the effect of lowering the prices of patented medicines. This was evident where the author Yamey was quoting Justin Forsyth [Oxfam's director of policy] as having said that-

> '[t]he World Trade Organization must change the rules that the drug industry is now using to cripple cheap, local competition, which in turn is inflating the cost of new and patented medicines.' [24]

Yamey cited the example of Indian generic drugs manufacturer, Cipla, who had announced that it would be selling triple combination HIV therapy to the non-governmental organization (NGO) Medicines without Frontiers for $350 per patient per annum, the cost of which to governments would be $600 per patient per annum. In response to this, the author says that, five major drug companies

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[20] *Ibid* see note 11, at para 6
[21] Decision of the General Council WT/L/540 and Corr.1 of 1 September 2003 **Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health**
[22] *Ibid* see note 21, at the fifth pre-ambular paragraph
[23] *Ibid* see note 15, paragraph (f) of same provides that where a WTO member seeks to issue compulsory licenses for the manufacture of generics of patented drugs, such licensing shall be predominantly for the supply of the domestic market of that member, whereas, paragraph (h) provides for the remuneration of the right holder whom such compulsory license would have been issued over his patented product.
[24] Gavin Yamey, US trade action threatens Brazilian AIDS programme, published in the British Medical Journal on 17 February 2001 and available from www.findarticles.com/p/articles/mi_m0999/is_7283_322/ai_71350531

then promised to cut the costs of their HIV drugs in the developing world, but still their prices would have been treble those offered by Cipla.

On the other hand, the waiver, by the Decision, of the requirement for the payment of adequate remuneration as per paragraph (h) of article 31 of TRIPS, would enable developing countries manufacturing generic drugs to do so with the lesser burden of having to pay hefty royalties to the patent owners.

**(iii)** ***Amendment of the TRIPS Agreement***

On 6 December 2006 WTO members approved changes to the TRIPS Agreement making permanent the August 2003 'waiver' *supra*.[25] This General Council Decision (hereinafter referred to as the 'December 2005 Decision') is a landmark one in that for the first time, a core WTO agreement will be amended. The effect of the December 2005 Decision is to transform the August 2003 'waiver' into a permanent amendment of the TRIPS Agreement. The WTO press release intimates that the amendment is designed such that it will match the 2003 waiver as closely as possible. To this end, delegations were involved in intricate legal discussions aimed at ensuring that the legal meaning and weight are preserved as exactly as possible.

The decision has brought great glee to developing countries and has been celebrated extensively. For example, the WTO Director-General [Pascal Lamy] is quoted as having said that the agreement to amend the TRIPS provisions confirms that members of the WTO multilateral trading system are determined to ensure that the system contributes to the humanitarian and development goals of the organization. Mr Lamy stated, further, that the decision gives him personal gratification as for a number of years, he had been involved in work geared towards ensuring that the TRIPS Agreement is part of the solution to the problem of ensuring that the poor have access to medicines.[26]

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[25] WTO: 2005 Press Releases Press/426 of 6 December 2005 on Intellectual Property, available at www.wto.org/english/news_e/pres05_e/pr426_e.htm

[26] *Ibid* see note 25, at para 5

Also celebrating the decision was Kenyan Ambassador Amina Mohamed, the chair of the WTO General Council. She has been quoted as having said that the main benefit of the decision is to ensure that the African nations have access to affordable medicines and that they are able to drive the price of the pharmaceuticals to an even lower level.[27]

Regarding the fear that the decision might be abused to undermine patent protection, the chair had soothing words designed to allay these fears. She alluded to the fact the members had a common understanding on how the decision was to be interpreted and implemented. She reiterated, also, that the decision would be used in good faith in order to deal with public health problems and not for industrial or commercial objectives, and that issues such as preventing the medicines getting into the wrong hands would be afforded the importance they deserve.

I have a feeling, however, that this is easier said than done as, in practice, there will always be that unscrupulous element in society which is bent on making a quick buck by any means necessary. As such, there will have to be strict measures in place to deal with those who will violate the provisions of the decision.

It should be pointed out at this stage that it is not all rosy and plain-sailing in that there are still those who are sceptical about the ability of the decision to work out as smoothly as planned. For instance, Ellen 't Hoen [the coordinator of the Globalisation Project of the Access to Essential Medicines Campaign of Me`decins Sans Frontieres (MSF)] had earlier criticised the August 2003 waiver as being 'overly cumbersome and inefficient'. She said that there was no experience of the mechanism being used and that not a single patient had benefited from its use despite the fact that newer medicines, such as second-line AIDS drugs, were priced out of reach of poor patients.[28] As such, it will

[27] Gustavo Capdevila, TRADE: Activists Take Issue with WTO Decision on Cheap Drugs, published on 7 December 2005 on the Inter Press Service News Agency website, at http://ipsnews.net/news.asp?idnews=31330

[28] *Ibid* see note 27

be paramount for members to find a way of transforming what is good, on paper, to actual provision of affordable drugs to the masses in the developing world.

't Hoen complained, further, that MST is already experiencing what she termed a 'steep increase' in their projects. She stated that they pay between 5 and 30 times more for second-line AIDS drugs to treat patients who need newer drugs due to the emergence of resistant strains of the disease.[29]

### (iv) *Implications of the TRIPS-related Developments in the Rest of the World*

The Canadian HIV/AIDS Legal Network in its paper[30] observed that as at present, India, Brazil and Thailand have been among the biggest generic producers of AIDS drugs, both for their own domestic consumption and for export. It alleges, further, that this production has been helpful in making AIDS drugs available to developing countries at affordable prices, and that competition created by these generics had the effect of reducing the price of many drugs from as much as US$15 000 per annum per person for a course of combination treatment to as little as US$150 per annum per person. This serves only to buttress more the point made earlier on the effect of generic competition on the price of drugs.

The paper singles out a few examples of how the new developments related to the TRIPS Agreement will affect the price and consequently availability of drugs for developing countries. The point of departure here is Indian law which in the period before 1 January 2005 did not recognize patents, thus allowing for the manufacture of generic drugs by companies in her pharmaceutical industry.[31] Thereafter, India's transition period to adapt to the TRIPS Agreement came to an end and the Indian parliament, in March 2005, passed laws amending their Patent Act to make it compatible with

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[29] *Ibid* see note 27
[30] Canadian HIV/AIDS Legal Network, Intellectual Property and Access to HIV/AIDS Treatment Case Studies, published on 1 August 2006
[31] *Ibid* see note 30 at page 1

TRIPS. The Canadian paper *supra* highlights the point that for first-line drugs that were already in the public domain pre-1995, Indian manufacturers can continue making generics of same. However, for second-line drugs which were manufactured after the entry into force of the TRIPS Agreement in 1995, for Indian companies to produce generics of same, they will need a compulsory license or similar authorization.

The paper stresses that without the necessary authorization to make the production of generics legal, the price of drugs will be the monopoly price that the patent owners can charge, in view of the absence of competition from generic drugs. It is also averred here that these second-line drugs are nearly 10 times more expensive than first-line drugs, and will be increasingly needed as resistance to the first-line drugs emerges. It is argued, further, that in addition to the procedural hurdles and uncertainty under the new rules on compulsory licensing, the issuing of such licenses by developing country governments will be made difficult by the inevitable political and economic pressures exerted by both brand-name pharmaceutical companies and countries like the US seeking to protect the interests of their industries. An example of this was cited by the author James Love in his article[32] where the US government embarked on the use of economic threats to force the Government of South Africa to amend its proposed Medicines and Related Substances Act which was aimed at promoting the availability of more affordable AIDS drugs via parallel imports and compulsory licensing. This, the author says, came in the form of the US cutting aid to South Africa in 1998 followed by the denial of tariff breaks on exports later in the same year, and, finally, placing South Africa on the 'watch list' in 1999.

The paper closes by saying that India is but one important example of how implementing TRIPS was likely to restrict existing sources of supply for lower-cost generic drugs that many developing countries like Botswana need to import. In this way, the paper emphasises that even those countries that are

[32] Notes on the USTR watch Lists and Reports, published in 1999 and available at http://cptech.org

not yet required to make their legislation compatible with TRIPS will feel the pinch if they need to import generic drugs from countries such as India where compulsory licensing is now required in order to export in any significant quantity.

Next, the paper looked at the example of Brazil whose government responded to the HIV/AIDS scourge in a manner that is now considered a model program in that it provided free treatment to [as at 1 August 2006] one hundred and sixty thousand (160 000) patients. This was made possible by Brazil's capacity to manufacture generic AIDS drugs, particularly first-line drugs which were developed before Brazilian law was amended in 1996 to make it TRIPS compatible by recognizing patents.[33] However, it is conceded that the problem *vis a vis* second-line drugs alluded to with regards to India is equally applicable here.

As a further example of how competition from generic drugs can cause a drop in prices of branded drugs, the authors cite the example of the ARV Kaletra (lopinavir + ritonavir), made by the US-based multinational Abbot Laboratories who, in 2005, was forced to drop the price of the said drug. This the Brazilian government achieved by issuing a threat to the US company to drop its price or face compulsory licensing of its patented product so that it could be distributed domestically and at a cheaper price. Abbot eventually relented and agreed to fix a lower price for a period of 6 years in exchange for Brazil agreeing to forego using generics or seeking further price reductions.

The authors look at the impact of the amendments to TRIPS from the point of view, also, of developed or high-income countries. The paper acknowledges the positive steps taken by the EU and Canada in an attempt to abide by the 2003 waiver and the 2005 decision *supra*. However, they are quick to point out the double-standards being applied by the US in an effort to protect its pharmaceutical industry. In this way, the authors say that 'countries that have tried to limit or balance patents with other public policy goals such

[33] *Ibid* see note 30, at page 2

as access to medicines inevitably run into opposition from the US as well as other rich nations where powerful drug companies are based.'[34]

The paper states, further, that the US's common objectives in concluding free trade agreements (FTAs) with other countries are to 'limit the potential exclusions from patentability, to prevent parallel importation, and to limit the grounds on which compulsory licensing may be granted (such as allowing it only in "emergency" situations)'.

In addition, the authors say that the US negotiates for 'data exclusivity' provisions which prevent any use of scientific data submitted by the original patent-holder in getting market approval. This would entail more burden and expense on the manufacturers of generic drugs in that they would now have to carry out scientific tests to come up with their own data. This is, arguably, running counter to what the 2003 waiver and the 2005 decision had intended. As an example, the authors here cite the on-going negotiations on the US-Thailand FTA.[35] Here, they aver that rules on 'data exclusivity' would require generic drug manufacturers to conduct their own clinical trials of the safety and efficacy of their 'new' drugs, rather than being able to use data submitted by the brand-name companies.

In conclusion, the authors point out a few important things pertaining to the accessibility and affordability under the TRIPS Agreement *vis* that*:*

(a) the recent developments in India, Brazil and Thailand illustrate how access to lower-cost generic drugs could become even more difficult in future;

(b) the WTO waiver of 2003 and decision of December 2005, ostensibly aimed at loosening the TRIPS patent rules to help secure access to medicines, are untested as yet and will be worth little if no further action is taken;

[34] *Ibid* see note 30, at page 4
[35] *Ibid* see note 30, at page 3

(c) new bi-lateral and multilateral trade agreements that impose 'TRIPS-plus' restrictions must be rejected;

(d) governments must be willing to use compulsory licensing to secure lower-cost medicines for patients in their own countries and abroad, and make the necessary legislative changes that may be required in their domestic law;

(e) for those countries [such as Botswana] without domestic capacity to manufacture generics, it is important that supplier countries adopt legislation to allow easy compulsory licensing for export, learning from and improving upon models such as the legal reforms adopted in India and other jurisdictions.[36]

Basing on the above, only time will tell whether the TRIPS Agreement can deliver medicines to those afflicted by AIDS in Botswana and other developing countries. In the meantime, however, we would do well to look at other avenues of making drugs accessible at affordable prices. In this direction I would now like to turn my attention to antitrust or competition law. The Republic of Botswana currently has no legislation on competition. However, in August of 2005, the Botswana Parliament approved the National Competition Policy for Botswana whose main objective is to prevent and redress any anti-competitive practices and conduct by firms, to encourage competition and the efficient use of resources, to promote investment, and to broaden choices and stabilise prices.[37] A Competition Bill is currently being drafted with the help of the United Nations Centre for Trade and Development (UNCTAD).

[36] *Ibid* see note 30 at page 5
[37] National Competition Policy for Botswana, published by the Ministry of Trade and Industry in July 2005, at pages 6 and 7

## CHAPTER TWO

### INTERFACE BETWEEN INTELLECTUAL PROPERTY RIGHTS AND COMPETITION LAW

The one thing that the Botswana competition law will have to take into account is the interface between intellectual property rights and competition law. This is very important especially with regard to the issue of pharmaceutical products and the patents held by the big multinational companies over them. Lawrence Reyburn, in his writing,[38] acknowledges this interface. He says that it is often claimed that there is an inherent conflict between the anti-monopoly bias of the competition system and what is perceived as a pro-monopoly bias of the intellectual property system. If this is the case, then it is implied that there has to be a yielding of ground by one where the other can assert primacy.

However, the author goes on to say that there is another level where the two, competition law and intellectual property rights, can co-exist in a manner that is complementary to one another in promoting economic efficiency and hence, ultimately, public wellbeing. Viewed from this angle, the author states that competition law should recognise and acknowledge the legitimate ambit of intellectual property rights, and that they embody economic and legal powers which are natural and healthy in an active and efficient economy, in the same way that monopolies which arise from superior efficiency and not from abuse of power are seen as legitimate in competition theory. This is a given as will be illustrated throughout the course of this paper, the essence of which is to buttress the point that monopolies are well and good as long as they do not establish market power which may breed abuse of dominance which is proscribed by section 8 of the South African Act.[39]

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[38] Lawrence Reyburn, Competition Law of South Africa, at Chapter 11 "Interface with Intellectual Property", last updated by Philip Sutherland on 31 August 2004

[39] The Competition Act of 1998

This point is also supported by the Competition Commission of South Africa, in its publication,[40] where it is said that both intellectual property laws and competition law have the same aim, that of the advancement of society and consumer choice. The Commission makes the point that intellectual property rights are granted to afford the owners the opportunity to recoup their innovation costs, and therefore have a pro-competitive benefit of keeping the market for innovation profitable and alive. The Commission states, further, that competition authorities will usually approach cases where there is an interface between intellectual property rights and competition law with a distinct competitive bias in favour of the owner of the intellectual property right. The precursor to this is that this does not mean that the anticompetitive effect of the exercise of an intellectual property right may not be found to outweigh the pro-competitive gains from granting intellectual property rights. This is the point at which the competition authorities should intervene. On a personal note, I feel that as an addition to this there should be lee-way to allow for the authorities in a particular country to act in the preservation of life as a matter of public policy. I will endeavour to deal with this argument in greater detail in the Chapter Three on 'Accessibility and Affordability – the Reach of Competition Law'.

The two writings [those of Reyburn and the Competition Commission of South Africa] alluded to in this part of my paper are agreed on the fact that interfaces between intellectual property and competition law, to a large extent, take place within the scope of licensing agreements where the owner of the intellectual property licenses the right to use the intellectual property to licensees under certain conditions. This aspect I will deal with in more detail further into my paper as it is very important to developing countries *vis a vis* getting affordable antiretroviral drugs from big multinational patent owners or alternatively from generic drug manufacturers who will require licenses to come up with the required cheaper drugs. The Commission makes an

[40] Competition News, Edition 4, June 2001 which can be found in the Commission's website at www.compcom.co.za

important observation to the effect that these licenses will invariably include such conditions as output constraints and market sharing which would raise the concern of competition authorities. The Commission says that licensing is widely regarded as very pro-competitive. This, they say is so as further improvements can be made to the technology and thus leading to further innovation taking place. This issue of licensing, as will be seen in this paper, is not as straight forward as one would think. It brings with it other ancillary matters such as refusal to deal, the essential facilities doctrine, and voluntary issuing of licenses. There are various presumptions relating to the intellectual property owner's extent and reach of his implementation of his rights as will be illustrated when analysing the decided cases in the United States of America (US) and the European Union (EU). Also addressed will be the question whether these presumptions can be rebutted and if so, upon presentation of what kind of evidence. This comparative analysis of laws in different jurisdictions will go a long way in assisting Botswana and other developing countries in terms of adopting the good practices in drafting her competition legislation by looking at the experiences of others.

Reyburn made a point to the effect that one short-coming of the South African Act is that it does not make sufficient recognition of intellectual property rights. He observed that the only express recognition of intellectual property rights is contained in s10 (4) dealing with exemptions from the general prohibitions regarding restrictive and abusive conduct.[41] No inkling is given in s10 of the principles which should be applied when applications regarding intellectual property rights are considered. Botswana and other developing countries should be wary of this and do all they can to avoid this

[41] S10 (4) specifically reads as follows:

> 'A firm may apply to the Competition Commission to exempt from the application of this chapter [Chapter 2: Prohibited Practices] an agreement or practice, or category of agreements or practices, that relates to the exercise of intellectual property rights, including a right acquired or protected in terms of the Performers' Protection Act, 1967 (Act No. 11 of 1967), the Plant Breeders' Rights Act, 1976 (Act No. 15 of 1976), the Patents Act, 1978 (Act No. 57 of 1978), the Copyright Act, 1978 (Act No. 98 of 1978), the Trade Marks Act, 1993 (Act No. 194 of 1993) and the Designs Act, 1993 (Act No. 195 of 1993).'

pitfall. The Commission, on the other hand, carried out research on other jurisdictions' approaches to the interface between intellectual property rights and competition law in order to establish a framework for consistent competition analysis in the case of such an interface. It was found that in the case of the two jurisdictions evaluated *vis* Canada and the US, both have comprehensive guidelines on how to assess cases with the said interface.

The US Department of Justice: Antitrust Division and Federal Trade Commission (being the US agencies) jointly issued guidelines with respect to the licensing of intellectual property. The guidelines state that standard antitrust analysis applies to intellectual property, and that intellectual property is no more or less subject to scrutiny from antitrust agencies than any other property. This is a great stride taken in the direction of recognising intellectual property rights in the US antitrust laws.

I will endeavour to deal with the Canadian guidelines in much more depth than I did with the US ones.[42] The Commission document avers to the fact that the Canadian guidelines stress the earlier highlighted point that competition law and intellectual property rights are both necessary for the efficient operation of the marketplace, as both wish to achieve a similar aim *vis* that of promoting a competitive marketplace. The Commission document highlights the fact that under the general provisions of the Canadian Competition Act, the mere exercise of an intellectual property right is no cause for concern as the unilateral exercise of the intellectual property right to exclude does not violate the provisions of the Act – no matter to what degree competition is affected. However, it is brought to note that the Bureau does apply the general provisions when intellectual property forms the basis of arrangements between otherwise independent entities, to use or enforce intellectual property rights when the alleged competitive harm stems from such an arrangement and not from the exercise of the intellectual property right. I fail to understand the wisdom in this reasoning in that had the

[42] The Canadian Competition Bureau released their Intellectual Property Enforcement Guidelines in 2000

complained of act been perpetrated by an individual it would not have been unlawful, but just that there would have been collusion in perpetrating the same act makes it unlawful.

The Commission document states that the Bureau's approach is that the mere exercise of an intellectual property right is not an anticompetitive act, but it acknowledges that there is a possibility that under very rare circumstances,[43] the mere exercise of an intellectual property right may raise competition concerns. Section 32 of the Canadian Act requires that certain circumstances be met and that, *inter alia*, the competitive harm should follow from the refusal to license. Should the requirements be met, the Federal Court is to balance the interest of the system of protection of intellectual property and the incentives created by it against the public interest in the market under consideration and competition in general. This is one paramount consideration that Botswana should take into account when drafting her competition law so as to avoid future confusion and authorities or courts arriving at varying decisions over cases with more or less similar facts. In reaching the above conclusion, it is said that the Bureau should have first determined that the holder of the intellectual property is dominant in the relevant market and that the intellectual property is an essential input, and that the refusal to license prevents competition in the relevant market. Secondly, the Bureau should have been satisfied that the refusal to license has a stifling effect on further innovation and that by invoking a special remedy against the intellectual property right holder, the incentive to invest in innovative markets will not be adversely affected.

The Commission document states that the approach followed by the Canadian Competition Bureau seems applicable to the South African legislative and economic circumstances. The document goes further to say that the methodology followed does not differ from the one that is the standard competition analysis implemented by the Competition Commission

[43] As set out in s32 of the Canadian Competition Act (2001)

and thus the approach could be implemented with success in the South African situation. I don't know whether this is synonymous with a call for the South African Act to be amended in line therewith. However, since it is felt that this is the best practice, then it would be advisable for Botswana to adopt same after having made the necessary legislative and economic analysis of the prevailing situation in Botswana. The document *supra* listed the following as some of the principles the Commission in South Africa would consider when analysing a situation with an interface between intellectual property rights and competition law:

> '1. Competition law should recognise the basic rights granted under intellectual property law. The creation and maintenance of innovation markets are necessary for economic progress and development;
>
> 2. Intellectual property does not necessarily create market power;
>
> 3. A practice involving intellectual property should not be prohibited if the practice leads to a less anticompetitive situation than without the said practice; and
>
> 4. The long-term pro-competitive benefits should outweigh the short-term "anti-competitive" effects of intellectual property rights.'

I deem it necessary to touch on this important point of when an interface between intellectual property rights and competition law would justify interference by the competition authority as the latter part of my paper will be based on licensing *vis a vis* the protection of patents held by multinational companies over antiretroviral drugs and how competition law can be used to deal with same and how this can lead to a reduction of prices of aids medicines which in turn will lead to accessibility of the said medicines in Botswana and other developing countries.

## CHAPTER THREE

## ACCESSIBILITY AND AFFORDABILITY – THE REACH OF COMPETIOTION LAW

It is very important to make a detailed analysis of how effective enforcement and strong competition advocacy can positively impact the access to drugs for the poor in Botswana and other developing countries in a similar predicament *vis a vis* the HIV/AIDS pandemic. On this note I will endeavour to use the South African, Brazilian, and Indian examples to see how competition law was used to positively influence pharmaceutical companies to make aids drugs accessible to the poor at reasonable prices.

(i) *The case of Hazel Tau and Others vs GlaxoSmithKline South Africa (Pty) Ltd and Boehringer Ingelheim (Pty) Ltd*

According to the complainant's statement of complaint,[44] the basis of the complaint was threefold as will be demonstrated shortly. I would first like to introduce the respondents in the complaint *vis* GlaxoSmithKline (hereinafter referred to as 'GSK') and Boehringer Ingelheim (hereinafter referred to as 'BI'). GSK is a company duly incorporated under the laws of South Africa and was cited because to the best of the complainants' knowledge it had and exercised the exclusive right to market and sell GlaxoSmithKline antiretroviral medicines (ARVs) in South Africa, as the South African representative of the GlaxoSmithKline group of companies. GSK had the exclusive right to market and sell the following ARVs in South Africa:

(a) Zidovudine (AZT), branded as Retrovir®;
(b) Lamivudine, branded as 3TC®;
(c) Abacavir (ABC), branded as Ziagen®;
(d) Amprenavir, branded as Preclir®;
(e) AZT/lamivudine, branded as Combivir®; and
(f) AZT/lamivudine/ABC, branded as Trizivir®.

[44] Statement of Complaint in Terms of Section 49B(2)(b) of the Competition Act 89 of 1998, which is available from the website of the Treatment Action Campaign at www.tac.org.za

BI was also a company registered under the laws of South Africa, and which, to the best of the complainants' knowledge, had the exclusive right to market and sell the ARV nevirapine—branded as Viramune®—in South Africa. BI was a South African operation of the CH Boehringer group which is a research-based group of pharmaceutical companies headquartered in Ingelheim, Germany. It was important that the complainants chose to initiate proceedings against these two companies as AZT, lamivudine, and nevirapine were the commonly used ARVs as part of the same triple-drug regimen.[45] The complainants' focus was on GSK and BI because the two companies not only charged much higher prices than generic drug manufacturing companies, but also vigorously enforced their patent rights in South Africa.

The particulars of the complaint were, first and most important, that respondents had engaged in excessive pricing of ARVs to the detriment of consumers, as prohibited by s8(a) of the Competition Act, 89 of 1998,[46] and that the excessive pricing of ARVs was directly responsible for the premature, predictable and avoidable deaths of people living with HIV/AIDS, including both children and adults.

Secondly, the complainants alleged that in so far as the ARVs were concerned, the respondents were dominant firms as contemplated by s7 of the Act.[47] In the result, the prohibition in the Act against excessive pricing to the detriment of consumers is applicable. The relevant markets in which dominance is alleged are detailed below.

Lastly, the complainants alleged that the respondents satisfied the threshold requirements in s6 of the Act[48] in that in the 2002 financial year, the gross revenue of each of the respondents from income in, into or from South

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[45] As per document released by the TAC in 2003 titled: 'Reducing the Prices of Anti-retroviral Medicines Answers to Frequently asked Questions' and which is available at www.tac.org.za

[46] Section 8(a) reads: ' It is prohibited for a dominant firm to –

(a) charge an *excessive price* to the detriment of consumers; …'

[47] Section 7 states that a firm is dominant in a market if it has at least 45% of that market, or if it has at least 35%, but less than 45%, of that market unless it can show that it does not have *market power*, or if it has less than 35% of that market but has *market power*.

[48] Section 6 provides *inter alia* for the Minister of Trade and Industry to determine a threshold of annual turnover or assets below which Part B of the Act on 'Abuse of Dominant Position' would not apply.

Africa, arising from the transactions set out in item 3(1) of the Schedule to the Determination of Threshold in terms of s6(1) of the Act, had exceeded the threshold of ZAR 5 million as contained in Government Notice 562 in *Government Gazette* 22128 dated 9 March 2001.

Following every complaint there has to be relief sought, and in this particular case the complainants sought relief in the following terms[49] in accordance with the provisions of the Competition Act:

(i) That after investigation in due course, the Commission refer the complaint to the Competition Tribunal in terms of s50(2)(a) of the Act;[50]

(ii) that, upon a finding of the existence of a prohibited practice in terms of the express provisions of s8 of the Act *supra*, the Tribunal order that the excessive pricing practice cease with immediate effect by virtue of the power granted it by s58(1)(a)(i) of the Act;[51]

(iii) that the Tribunal declare the respondents' conduct a prohibited practice for purposes of damages claims by all persons who can establish that they have suffered loss or damage as a result of the prohibited practice concerned in terms of s58(1)(a)(v)[52] read with s65of the Act;[53] and

(iv) that the Tribunal impose an administrative penalty, on GSK and BI, of up to 10 *per cent* of their annual South African turnover in accordance with s58(1)(a)(iii)[54] as read with s59 of the Act.

On 16 October 2003, the Competition Commission announced that they had decided to refer the complaint to the Competition Tribunal. They released a press statement stating that GSK and BI had contravened the Competition

[49] This was contained in paragraph 103 *et al* of the complainants' Statement *supra* see note 12
[50] Section 50(2)(a) is to the effect that the Commission must, within one year of its receipt of a complaint, refer a complaint to the Competition Tribunal if it determines that a *prohibited practice* has been established.
[51] Section 58(1)(a)(i) gives the Tribunal power to issue an order interdicting any *prohibited practice.*
[52] Section 58(1)(a)(v) gives the Tribunal power to issue an order declaring the conduct of a firm a *prohibited practice* for the purposes of s65 of the Act.
[53] Section 65 makes provision for the need for other courts to refer competition law issues to the Tribunal before dealing with the merits thereto. This is particularly important for litigants who may want to sue for damages based on claims arising from breaches of the Competition Act.
[54] Section 58(1)(a)(iii) empowers the Tribunal to issue administrative penalties pursuant to s59 of the Act.

Act of 1998 by abusing their dominant positions in the market. The Commission found that GSK and BI had engaged in the following forms of prohibited conduct:

(a) Excessive pricing to the detriment of consumers;

(b) Denying a competitor access to an essential facility; and

(c) Engaging in an exclusionary act.[55]

The Commission's findings went beyond the original complaint. The initial complaint only asked the Commission to find that the drug companies had engaged in excessive pricing. The Commission had investigated the complaint and found evidence to support the referral to the Competition Tribunal on these two additional grounds, both of which dealt with the failure of GSK and BI to give licenses to generic manufacturers.

The Commission had decided to ask the Competition Tribunal to license generic competitors. By opening up the market to generic competition, the Tribunal would have ensured that people in South Africa got access to a sustainable supply of affordable ARVs.

The TAC paper seeks to stress the point that it is important to understand that these were merely findings of the Competition Commission after its yearlong investigations, and that they were not legal rulings. It is the role of the Competition Tribunal to make orders against GSK and BI if, after hearing arguments and considering the evidence, it concluded that the Competition Commission's findings were correct.

Nevertheless, the Competition Commission’s findings were significant, as they eventually put pressure on GSK and BI to lower their prices and to give licenses to generic manufacturers.

It is such a pity (especially for students of law), depending on which way you look at it, that the case did not go all the way to be heard by the Tribunal as a settlement was reached between the complainants and the pharmaceutical companies whereby the two companies issued voluntary licenses to a manufacturer of generic drugs (Aspen) for it to use the two companies’ patents to come up with generic medicines. The conditions of the licenses, however, were very tight and I do not wish to concern myself too much with them.

[55] *Ibid* see note 45

On the same day that the Competition Commission announced that it would refer the matter to the Tribunal, GSK extended its licensing agreement with Aspen such that the latter could sell their AZT and lamivudine products to the private sector and also export the medicines to all countries in sub-Saharan Africa. The TAC observed in addition that, GSK reduced its ARV drug prices to the public sector, NGOs and companies providing medicines to their employees. However, their private sector prices remained excessive.

Of concern, however, was that neither GSK nor BI had yet allowed any other generic company to have a license to produce or import generic ARVs. In addition, neither GSK nor BI had indicated that they were prepared to do so. The TAC felt that this was problematic for three reasons *vis*:

> '(a) that more generic companies were urgently needed to ensure proper competition among drug companies. Only proper competition would ensure that drug prices reached their lowest possible amount and would stay there;
>
> (b) at least two generic companies produced a single pill containing three ARVs. This was very important because patients could then take one pill twice a day instead of many pills. This had been shown to improve adherence to medicines and ultimately patient health. However, since all the ARVs that were in the pill (which happened to be d4T, lamivudine and nevirapine) were patented in South Africa, the generic companies could not legally sell the medicines in South Africa unless they got licenses to do so. Until that point, only one company (BMS) had agreed not to enforce its rights in its patented ARVs, one of which was d4T. But until GSK did the same (or grants licenses to generic companies) for lamivudine, and BI the same for nevirapine, this important combination ARV drug could not be sold in South Africa; and
> (c) the TAC made a further observation that at least one generic company produced another combination pill containing three ARVs (AZT, lamivudine and nevirapine). But the company could not sell this important pill in South Africa until such a time that it got a license to do so.'[56]

Of great interest to me is the findings made by the Commission and how they would lead to a more permanent and sustainable solution. All we can do for now is to ponder as to how the Tribunal would have dealt with the issues. I will endeavor to address the issues next by making a comparative analysis with decided cases in the US and Europe.

[56] *Ibid* see note 45

(ii) *The Issue of Denying a Competitor Access to an Essential Facility*

As earlier alluded to, it is unfortunate that the South African case of Hazel Tau *supra* did not go before the Tribunal for determination of the issue whether intellectual property, in South African jurisprudence, can be said to amount to an *essential facility* in terms of the Act which prohibits a *dominant firm* from refusing to give a competitor access to an *essential facility* when it is economically feasible to do so.[57] The Act defines an *essential facility* at s1(1)(viii) under CHAPTER 1 '**DEFINITIONS, INTERPRETATION, PURPOSE AND APPLICATION OF ACT'**.[58]

The question for determination now is whether intellectual property can be said to be an 'infrastructure or resource' as intended by the wording of the Act. I will attempt to answer this question by looking at the comparative jurisprudence of decided cases in South Africa, Europe, and the US. This so as to see whether the Botswana courts would be justified or not in deciding the issue, whichever way they may determine it. It has been said by some legal commentators that under the *essential facilities* doctrine, 'the monopoly owner of an "*essential facility"* for competition may be forced to give access to that facility to competitors on reasonable and non-discriminatory terms'.[59]

The authors went on to analyse a few decided **US cases** on the *essential facilities* doctrine and came to the conclusion that in each of the cases the defendant owned a facility that could not feasibly be duplicated, and also participated in a competitive downstream market that required access to the facility. From this it is clear that the doctrine can only be used in the case of a plaintiff who is in the relevant market in competition with the owner of the facility.[60] As such, it is not clear how in the case of a small developing country like Botswana, where there are no companies with the requisite capacity to manufacture generic ARVs, the doctrine will be of use. Unless the government takes positive steps to assist entrepreneurs in the form of public private partnerships (PPPs) whereby they will engage in a joint-venture to get the

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[57] *Ibid* see note 46, at s8(b) of the Act

[58] Section 1(1)(viii) states thus - '***essential facility*** means an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers;'

[59] Herbert Hovenkamp, Mark D. Janis, & Mark A. Lemley in their article, UNILATERAL REFUSALS TO License, published in the Journal of Competition Law and Economics on 24vFebruary 2006

[60] See Intergraph Corp. v. Intel Corp. 195 F.3d 1346 (Fed. Cir. 1999) at 1356-59

process of manufacturing started, I see the reach of competition law being compromised where it would have been of great assistance.

(a) Going back to the **US cases**, the authors cited examples of the cases of *Terminal Railroad*,[61] *Otter Tail*,[62] and *MCI*.[63] In *Terminal Railroad*, the facility owned was a key bridge over the Mississipi River and accompanying rail yard which the owners, a group of railroads, refused to give competing railroads use of the facility. In *Otter Tail*, the facility in issue was transmission lines into a municipality which the owner public utility refused to allow the municipality to 'wheel' power over those lines from outside plants because the utility itself wanted to provide power to the municipality. Lastly, in *MCI* the pre-breakup Bell System refused to permit MCI to connect its long-distance calls to the Bell System's local phone exchanges. In this latter case the court formulated a four-part test for an essential facilities claim which, if made out, the defendant will be compelled to provide access to the facility on reasonable and non-discriminatory terms. The court laid down the test as follows:

> '(1) control of the essential facility by a monopolist;
> (2) a competitor's inability to duplicate the essential facility;
> (3) the denial of the use of the facility to a competitor; and
> (4) the feasibility of providing the facility.'[64]

The authors note that the test also offers a defence of legitimate business justification by permitting the defendant to show that it was not feasible to provide access to the facility. In this way, I would suppose, the pharmaceutical companies in the case of South Africa, Botswana and other developing countries would have to adduce tangible evidence of same, for instance, in the form of balance sheets showing, for example, that in light of the investment they would have made in research and development, it would not be economically feasible for them to avail the essential facility (in the present case being the patented formulae involved in manufacturing their ARVs) to their competitors,

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[61] United States v. Terminal R.R. Ass'n, 224 U.S. 383 (1912)
[62] Otter Tail Power Co. v. United States, 410 U.S. 366 (1973)
[63] MCI Comm. Corp. v. AT&T, 708 F.2d 1081 (7th Cir. 1983)
[64] *Ibid* see note 63, at pages 1132-33

being the manufacturers of generic medicines.

The authors view it important to add that, though the court in *MCI* and *Otter Tail* did not address the issue directly, withholding an essential facility is illegal only if it has the undesirable effect of foreclosing competition in the downstream market, and therefore of helping the defendant to acquire and maintain a monopoly in that market. This seems to imply that the claimant in an essential facilities claim would have the further onus of proving that failure or refusal by the owner to avail him the facility would lead to his not being able to continue business and therefore having a net negative effect on competition.

In closing on the US position, the authors express the view that the doctrine is dead in the US since the Supreme Court, in *Trinko,* distanced itself from the doctrine by claiming that it had 'never recognized such a doctrine'.[65] This US approach was reiterated by Harry First who, though conceding that intellectual property is now seen as essentially similar to tangible property, stressed that the 'inherent goods' aspect of intellectual property makes it prone to free riding leading to rights holders arguing that stronger protection is needed to achieve adequate returns and optimal levels of innovation.[66] This approach of developed countries runs parallel to what developing countries would like, *vis*, having a less stringent intellectual property rights regime. First went on to state that 'indeed the Supreme Court in *Trinko* accepts the idea that owners of monopolies should be given strong protection so as to promote innovation and allow maximum returns, because the opportunity to charge monopoly prices, at least in the short term is what attracts business acumen in the first place'. This line of thinking is hardly surprising coming from the land of free enterprise where profit maximization is the order of the day. Not to say that one can climb the moral high ground and seek to vilify the pharmaceutical companies for pricing their products excessively, after all they are in business to make profit. However, looking at the precarious position that Botswana and other developing

[65] Verizon Communications v. Law Offices of Curtis V. Trinko, 540 U.S. 398, 411 (2004)
[66] Contributions to discussions at the 'ANTITRUST AND INTELLECTUAL PROPERTY: DUTIES TO LICENSE, PARALLEL IMPORTS AND THE QUESTION OF DIFFERENTIAL TREATMENT FOR DEVELOPING COUNTRIES' Post-Fordham International Competition Policy Conference Saturday, October 3, 2004

countries find themselves in *vis a vis* the aids pandemic, from the point of view of care for humanity and the preservation of life, it would be wise to enact competition law that would take into account emergency situations which would give the competition authorities power to intervene and order that the pharmaceutical companies give licenses to manufacturers of generic drugs or allow for the importation of generic medicines from other developing countries with the capacity to manufacture same. However, a precursor to such a provision would have to be that it should not be left wide-open so as to invite its abuse by unscrupulous governments. It should be construed in a very narrow or restricted sense so as to guard against its abuse to the detriment of manufacturers of medicines.

The authors say that they are not aware of any case in which a US court has held that an intellectual property right was itself an essential facility that must be licensed on reasonable and non-discriminatory terms. They state further that although the cases present the issue, none of the courts directly addresses the issue of whether an intellectual property right can constitute an essential facility. This, in my opinion, leaves a ray of hope for the believers in that, so long as the court has not ruled expressly to the contrary, it cannot be said with certainty that an intellectual property right cannot constitute an essential facility. As such, I choose to disagree with the authors when they say the following:

> 'We believe the better view is that an intellectual property right itself cannot constitute an essential facility, and that the doctrine should not be applied to cases that seek access to an intellectual property right in any but the most unusual of circumstances.'[67]

I am only inclined to agree with them in the latter part of the statement which calls for the application of the doctrine to cases that seek access to an intellectual property right only in the most unusual of circumstances. This seems to buttress my earlier point that any provisions contemplated in the legislation of Botswana and other developing countries must guard against abuse.

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[67] *Ibid* see note 59, at page 15

(b) However, it is not all doom and gloom as **European Union (EU) case-law** holds a contrary opinion as will be shown hereafter that, unlike the US, there is no doubt that, in the EU, a refusal to license may raise antitrust liability and that the doctrine of *essential facilities* may be applied to intellectual property rights. In detailing the jurisprudence in the EU, I will refer to two articles on the subject, one authored by Francois Leveque[68] and the other, a report of proceedings where Rachel Brandenburger[69] (a partner in a law firm in Brussels) made a telling contribution. Brandenburger observed that the scope of intellectual property rights is a matter for intellectual property law while the exploitation of that right is a matter for antitrust law. This ties in well with the earlier stated position of where and when there can be an overlap between the two. As to the questions of whether intellectual property rights should be treated differently from other property rights and whether intellectual property rights can be an essential facility, the learned attorney observed that both the European Court of Justice (ECJ) and the US Supreme Court have been reluctant to confirm or deny the *essential facilities* doctrine. However, Brandenburger went on to point out that in the EU jurisdiction, an owner of intellectual property rights may be required to license his right to other users where there exists 'exceptional circumstances' to justify interference with the said monopolistic rights. This position of the law, to which Leveque agrees, was established in the *Magill* case[70] and further clarified in the later case of *IMS Health.*[71] The question as to what amounts to 'exceptional circumstances' was dealt with in *Magill* where copyrights were at stake and the blocking of a new product at the prejudice of consumers resulting from a refusal to license was considered, by the court, to be an 'exceptional circumstance'. The importance of this condition was underscored in *IMS Health* later on.

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[68] Leveque Francois, Innovation, Leveraging and Essential Facilities: Interoperability Licensing in the EU Microsoft case, published in the March 2005 edition of World Competition

[69] *Ibid* see note 66

[70] Cases C-241/91 P&C-242/91 P, RTE & ITP v. Commission [1995] ECR I-743, [1995] 4 CMLR 718, [1995] 1 CEC 400 (ECJ)

[71] Judgment of the ECJ of 29 April 2004 case C-418/01 IMS Health v. NDC Health, as yet unpublished; available at <http: www.curia.eu.int>

The court in *Magill* laid down the test by stating that –

> 'In order for the refusal by an undertaking which owns a copyright to give access to a product or service indispensable for carrying out a particular business to be treated as abusive, it is sufficient that three cumulative conditions be satisfied, *vis,* that the refusal is preventing the emergence of a new product for which there is a potential consumer demand, that it is unjustified and such as to exclude any competition on a secondary market.'[72]

The ECJ in *Magill*, in upholding an order by the Commission famously stated that-

> 'The exercise of an exclusive right by the proprietor may, in exceptional circumstances, involve abusive conduct.'[73]

Brackenburger made an observation that, in the *IMS Health* case, the court appears to have weakened the 'secondary market' requirement in saying that a potential or hypothetical secondary market would be sufficient to satisfy the test. The learned attorney also made a point that she thought there was uncertainty regarding the 'new product' requirement in that the court only stated that the party requesting a license must not intend only to duplicate the goods or services already offered [this, in my view, would pose a major stumbling block *vis-à-vis* the manufacturers of generic drugs in Botswana and other developing countries who would be merely be seeking the right to duplicate which would go against this requirement]. Brackenburger points out that, beyond this clarification, the court did not address what a new product is, whether slight improvements to a product constitute a new product, or whether the new product must be substantially different from the existing product. This presented a major challenge to the test in *Magill*.

[72] *Ibid* see note 70, at recital 38 of the judgment
[73] *Ibid* see note 70, at recital 50 of the judgment

Leveque, in addition, feels that though clarifying the picture, the decision in *IMS Health* also raises new questions concerning the scope of the *Magill/IMS Health test*. The author poses the following series of questions which he thinks beg to be answered –

> 'Is it [the test] specific to refusal to license copyrights? If so, what is the relevant test for patents? Does it [the test] address exclusively intellectual property rights? If so, why would the ECJ apply a different antitrust treatment to intellectual property from other forms of property? On the contrary, does it [the test] cover both tangible and non tangible essential facilities? If so, how are we to explain the evaluation of the ECJ towards a more restrictive view on the use of the essential facility doctrine?'[74]

The answer to the above questions, or an indication of a lack thereof was evident in the EU *Microsoft* case where the Commission avoided using the test altogether.[75] I shall now turn my attention to the *Microsoft* case which sought to introduce a new test for the application of the *essential facilities* doctrine to interfere with intellectual property rights. The facts of the said case were that in 1998 Sun Microsystems lodged a complaint with the EU Commission accusing Microsoft of breaching competition rules by denying it access to essential information on its [Microsoft's] Windows operating system. Six years on, in the Commission's decision of 24 March 2004, the Commission found Microsoft guilty of having infringed article 82 of the EC Treaty by refusing to supply Sun Microsystems and other rivals with the information they needed to offer compatible products.[76]

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[74] *Ibid* see note 68, at page 6

[75] Case COMP C-3/37.792, EC Commission v. Microsoft

[76] Article 82 of the EC Treaty reads thus-

'Any abuse by one or more undertakings of a dominant position within the Common Market or in a substantial part of it shall be prohibited as incompatible with the Common Market in so far as it may affect trade between Member States. Such abuse may in particular consist in:

(a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
(b) limiting production, markets or technical development to the prejudice of consumers;
(c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
(d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection to the subject of such contracts.'

In analysing how the Commission reached its decision, both Leveque and Brandenburger made some interesting observation. For instance, the latter poses the question whether Microsoft's refusal to provide seamless interface information to workgroup server rivals amounted to an exclusionary strategy or a simple refusal to deal? This is significant in that it will have an effect on the type of remedy to be ordered in the end. The learned attorney speculates that, if on appeal, the Commission could demonstrate that competitors had been prevented from developing better products than offered by Microsoft, and those would-be improvements were sufficient to constitute a new product, the court could possibly uphold the Commission's decision as a refusal to deal. Further, the learned attorney asserts that, the Commission could attempt, on appeal, to characterize the remedy as merely the disclosure of an industry standard, in which case a lower threshold than that provided by the *IMS/Health* test would seem appropriate. As to whether Microsoft engaged in an exclusionary strategy by ceasing to provide information to competitors that it had previously made available to, Brandenburger says that the Commission argued that Microsoft changed from a competitive course of action when it (Microsoft) did not have its own work group server, to a non competitive one after Microsoft developed a competitive group server. The learned attorney goes on to state, further, that if the Commission's decision relies on a theory of exclusionary strategy rather than a simple refusal to deal, the ramification may be that a potentially dominant supplier would be safer never to make information available in the first place. This, surely, would not be good for the competitive process.

In his analysis of the *Microsoft* case, Leveque states that the Commission in coming to its decision followed two lines of argument in demonstrating that the refusal to supply is indeed abusive. Firstly, the Commission attempted to establish that information on interface is an essential facility. Secondly, the Commission advocated that Microsoft's disruption in refusing to supply reflects a leveraging and foreclosure conduct. As a remedy to the abuse, the Commission has ordered Microsoft to give access to specifications of interface protocols. Leveque goes on to state that Microsoft feels that the information

required by Sun Microsystems is protected by several patents and such protection justifies its refusal to disclose, and that as a result, a compulsory licensing would annihilate its efforts of innovation.[77] Predictably, Microsoft appealed the Commission's decision before the court of First Instance which will not make a ruling until after about 2-3 years, and which decision would most likely lead to a chain of appeals instituted by the losing party. Also, Leveque has pointed out, there is a possibility that Microsoft and the Commission will settle out of court thus creating a situation whereby we would never know who was wrong and who was right *ala* the South African case of *Hazel Tau supra*.

The two analysts (Branbenburger and Leveque) are agreed as to the fact that in the *Microsoft* case, the Commission appeared to have moved away from the 'exceptional circumstances' test by examining all the circumstances surrounding Microsoft's refusal to supply rather than relying on an exhaustive checklist of exceptional circumstances. I am persuaded to agree with the two that this test is a sounder way of determining if 'exceptional circumstances' exist, to justify the intervention with an individual's intellectual property right, than is the *Magill/IMS Health* test which, *inter alia*, requires that there must be created a 'new product', without determining what will constitute a new product. This latter test would be hard to apply, especially in the case of the manufacturers of generic aids drugs in developing countries who, it can be said, make clones of the patented drugs without adding anything that would make them pass the 'new product' requirement in the *IMS Health* test. It must, however, be noted that the reason why the Commission did not attempt to address the 'new product' conditions was because the decision in *IMS Health* was still pending when the Commission issued the decision in *Microsoft*. In moving away from the test in *Magill*, the Commission made a claim to the effect that –

[77] Microsoft's Reaction: The European Commission decision in the Microsoft Case and its Implications for other Companies and Industries, April 2004 <http://www.microsoft.com/presspass/legalnews>

> 'Case-law suggests that the Commission must analyse the entirety of the circumstances surrounding a specific instance of refusal to supply and must make its decision based on the results of such a comprehensive examination.'[78]

Leveque states, further, that despite moving away from the test in *Magill*, the Commission is in no doubt that the *Magill* test is passed in the *Microsoft* case. In support of this, he cites the Commission's argument that Microsoft's refusal to supply had resulted and would continue to result in blockading new functions of operating systems to appear in the market. Further, he asserted, the Commission established that Microsoft limited technical development[79] and exemplified[80] how competitors offered new features in their products corresponding to consumer demand before Microsoft interrupted giving them information on interface. This latter fact is illustrative of the fact that Microsoft moved from being competitive to being anti-competitive once it had a server system capable of competing with those of its rivals. To me, this gives the antitrust authorities every right to interfere where the competitive process is likely to be harmed.

Leveque praises the Commission's innovative step in coming up with a new question to test, *vis*, does the refusal to license reduce the incentives to innovate in the whole industry? In clearer terms, is the negative impact of a compulsory license on a dominant firm's incentives to innovate outweighed by its positive impact on the innovation level of competitors? This examination is made by the Commission to reject Microsoft's argument defending that its intellectual property is an objective justification of its behaviour. As such, a similar provision would have to be drafted in the Botswana legislation to follow international best practices. On this, the Commission had the following to say-

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[78] *Ibid* see note 75, at recital 558
[79] *Ibid* see note 75, at recital 693-700
[80] *Ibid* see note 75, recital 841 and 842

> 'In view of these exceptional circumstances [indispensability of the input, risk of elimination of competition and negative impact on technical development to the prejudice of consumers], Microsoft's refusal to license cannot be objectively justified merely by the fact that it constitutes a refusal to license intellectual property. It is therefore necessary to assess whether Microsoft's arguments regarding its incentives to innovate outweigh these exceptional circumstances.'[81]

The Commission goes further to state that a detailed examination of the extent of the requested availing of information led them to the conclusion that, on balance, the possible negative impact of an order to supply on Microsoft's incentives to innovate is outweighed by its positive impact on the level of innovation of the whole industry, Microsoft included.[82] Should the Court of First Instance uphold the Commission's order, this will provide a valuable precedent for the courts in Botswana and other developing countries when dealing with similar issues of refusals to license. Therefore, in the case of pharmaceutical companies, the 'incentives to innovate' test would have to be passed for there to be intervention with an individual's intellectual property rights (be it copyright or patents). In doing this, the courts will have to carry out a factual analysis and decide each case as it comes in a 'rule of reason' kind of way, instead of having exhaustive rules or conditions to be met in a *per se* kind of approach. For example, this process will entail the disclosure of the balance sheets of the pharmaceutical companies so as to see how much they have expended in research and development to see whether compelling them to disclose their secret information would, in future, deter them from engaging in research and development for it being too expensive as against the meagre possible gains caused by interference with their exploitation of their intellectual property rights by antitrust authorities.

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[81] *Ibid* see note 75, at recital 712
[82] *Ibid* see note 75, at recital 783

In his expression of his preference for the 'incentives to innovate' test established in *Microsoft*, Leveque based the reasons for his choice on economic considerations in saying that the analysis of the incentive effects to test whether the market will be limited to the prejudice to consumers is much more relevant. Firstly, he argues that incentives to innovate are a good proxy of consumers' benefits and that economic theory predicts that wherever incentives are present firms will innovate to propose valuable improvements to consumers. Accordingly, he says that if firms see the opportunity to make money by investing in research and development, they will grab the opportunity. In closing this argument, Leveque says the following –

> '…, if a refusal to license reduces the incentives to innovate, we can infer that the technical development will be limited to the prejudice to consumers.'[83]

The author's second line of argument is that the incentive effects approach is suited to economic theory on intellectual property where the rationale of the rights is to provide incentives to innovate and to overcome the free-riding problem. He states that each firm will find it uneconomically beneficial to innovate if their inventions cannot be protected from copying, by rivals, through intellectual property rights. This scenario, it is contended, would lead to innovators not recovering their investment in research and development resulting in innovation not being a viable exercise. However, Leveque is quick to point out that intellectual property can also play a debilitating role in hindering innovation. An example of this would be where there are different complimentary innovations. The author says that the problem of there being no relationship between , on the one hand, changes in characteristics of the product and, on the other hand, values and costs of innovations in terms of the new product condition in the *Magill/IMS Health* test, the incentives balance test proposed in *Microsoft* provides the solution to dispose of this problem. He reasons as follows-

[83] *Ibid* see note 68, at page 9

> 'By definition, the antitrust order cannot be ruled if the compulsory license decreases the incentives of the whole industry. Therefore, where the order stops Firm A from investing, innovation 1 is not made and, as a result, innovation 2 does not emerge, neither. The incentives of the whole industry are lower than in the absence of compulsory licensing. The compulsory licensing is therefore not ordered.[84]

Leveque goes on to analyse the application of the incentives balance test in the *Microsoft* case. Here, the author expresses the view that the Commission's effort to achieve simplification in facilitating the demonstration of the *essential facility* doctrine is not robust. He questions whether *Microsoft* passes the new test of incentives balance. He agrees that in so far as the essential facility owner has to prove the existence of an objective justification, the burden of proof lies with Microsoft. However, he expresses doubts as to whether it is evident that compulsory licensing will decrease more Microsoft's incentives to innovate than it will increase rivals' incentives to innovate. Therefore, Leveque questions the manner in which the Commission reached its conclusion on this point. As such, a lesson that can be learnt for new legislation in Botswana and other developing countries is to try and make provision for the application of this test.

Leveque poses the question as to whether the connection of the new test with the condition of objective justification is relevant in *Microsoft*. He argues that according to him, the lack of objective justification refers, in the *essential facility doctrine*, to negative external effects (giving as an example, congestion which the mandatory access will cause). The author argues, further, that if third party access to an electricity grid or to an airport disrupts the functioning of the facility, the increase in competition may not worth the damage it causes. In such instances, I am agreed with the author, it would be economically unsound to order the access. The above is not peculiar to intellectual property rights as evident in the author's statement where he says-

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[84] *Ibid* see note 68, at page 10

> 'However, the specific feature of intellectual property in comparison with other forms of property is merely the absence of capacity constraints. In economic jargon, intellectual property is a non-rival good. Its use by one agent does not reduce consumption by others.'[85]

Notwithstanding this, the author re-states his view that as a required test to apply the *essential facility* doctrine to intellectual property, the approach based on incentives is more economically sound than the new product condition. The author though proceeds to criticise the doctrine by stating that it allows antitrust authorities to rectify the scope of intellectual property rights. This he thinks is not healthy as it will bring about uncertainty on the part of inventors as they will not know in advance whether their rights will be whittled down or upheld by competition authorities. As such they will not be able to estimate the return on their investments accurately, which will heighten legal insecurity which would then result in a reduction of incentives research and development efforts. Lastly, the author avers that forced access may facilitate collusion between competitors.

Legal commentators believe that the EU *Microsoft* case leaves a gap for the *essential facility* doctrine to survive and that the judgment in that case pushes the boundaries of the test as far as it can go.

(c) The only **South African** case worth mentioning in relation to the *essential facility* doctrine which went as far as the Competition Appeals Court is that of *Glaxo Wellcome vs. National Association of Pharmaceutical Wholesalers*.[86]

Here, the presiding judge Hussain JA [as he then was] made the important point that unlike the South African Act[87], neither article 82 of the EC Treaty[88] nor the US Sherman Antitrust Act makes any express reference to the expression 'essential facility'. Instead, the two pieces of legislation contain provisions relating to the general prohibition of abuse of dominant position, and the essential facility doctrine, as earlier demonstrated, in both jurisdictions is the

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[85] *Ibid* see note 68, at page 12
[86] *Glaxo Wellcome v National Association of Pharmaceutical Wholesalers* CASE NO: 15/CAC/Feb 02, can be accessed from the Tribunal website www.comptrib.co.za
[87] *Ibid*, see note 39
[88] *Ibid,* see note 76

result of judicial application of widely-framed norms directed at conduct amounting to the abuse of a dominant position. Thus, it would be advisable for Botswana and other developing countries in the process of formulating competition law to follow the South African example and make provision for the doctrine in legislation instead of leaving it to the whim of the courts to interpret and administer without any legislative guidance.

Before going into an analysis of the case, it is paramount to state that the case did not involve the application of the *essential facility* doctrine to intellectual property and the question of whether intellectual property can be an essential facility. Instead, what was in dispute was whether scarce goods or products could be an essential facility, a question which the court answered in the negative as will hereafter be demonstrated. In *Glaxo Wellcome*, the complainants were pharmaceutical wholesalers and distributors while the respondents were manufacturers of pharmaceutical products, a great deal of which were sold and distributed by the complainants. The gravamen of the complaint related to the conversion by the respondents of a company cited as the 8th respondent [Druggists Distributors-DD] from a wholesaler to a distribution agent on behalf of the respondent. This action resulted in the complainants continuing to supply the large volumes of the complainants' products except that the respondents stopped offering the complainants a discount of 17.5 *per cent* as was the custom. The complainants therefore objected to the respondents' decision to set up the distribution agent and sought relief against the respondents through the Act alleging that the latter had engaged in conduct prohibited by sections 4, 5, 8, and 9 of the Act.[89] The learned judge states that the complainants, in their referral, alleged conduct, on the part of the respondents, which, *inter alia*, amounted to:

[89] The said provisions proscribe conduct amounting to restrictive horizontal practices, restrictive vertical practices, abuse of dominance, and price discrimination by dominant firms

'(a) denial of access to an essential facility;

(b) the charging of excessive prices; and

(c) predatory pricing.'[90]

I shall confine myself to the allegation in (a) above, *vis*, the one of denial of access to an essential facility in accordance with s8(b) of the Act.[91] The learned judge observed that according to the complainants, the respondents' product constituted resources that could not reasonably be duplicated in accordance with the definition of the term in the Act.[92] In the learned judge's opinion, it is clear that the provisions of the Act do not support such an interpretation as 'resource' was not meant to be interpreted as products, goods or services. As such, the learned judge was not persuaded by the complainants' argument that pharmaceutical products qualify as essential facilities and resources for anti-trust purposes.

The learned judge is of the view, further, that the tribunal's approach together with the wrong interpretation relied upon by the complainants effectively gives s8(b) a wide meaning which broadens the scope of the said provision well beyond what was intended by the legislature. He is adamant in his understanding that the legislature intended, from the clear architecture of the Act, that there should be limits to the *essential facility* doctrine. The learned judge reasons that granting access to a dominant firm's facilities is a substantial intervention on the part of competition authorities and as such, widening the application and scope of the essential facilities doctrine can have harmful economic effects such as discouraging investment in infrastructure. This, the learned judge says, might lead to a scenario where investors will be reluctant to invest for fear of a third party demanding a 'free ride' on the fruits of such investment. The learned judge points out that the myriad of available decided cases do not favour a wide interpretation and application of the doctrine.

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[90] *Ibid* see note 86, para [10] at page 7 of the judgement

[91] Section 8(b) of the South African Competition Act Reads: 'It is prohibited for a dominant firm to –
(b) refuse to give a competitor access to an essential facility when it is economically feasible to do so;'

[92] Section 1(1)(viii) defines essential facility as 'means an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers;'

This led the court to hold as follows:

> 'Thus, whilst it is unnecessary, for purposes of this judgment, to define the ambit of section 8(b), I find that section 8(b) does not prohibit the conduct of refusing to supply scarce goods to a competitor. For reasons already stated, the phrase 'refuse to give a competitor access to an essential facility' does not mean 'refusing to supply scarce goods to a competitor', 'nor is section 8(b) a species of some more general refusal to deal (sic).'[93]

The court went on to state that for one to allege a contravention of s8(b), they will have to aver, in their complaint, that:

> '1. the dominant firm concerned refuses to give the complainant access to an infrastructure or a resource;
> 2. the complainant and the dominant firm are competitors;
> 3. the infrastructure or resource concerned cannot reasonably be duplicated;
> 4. the complainant cannot reasonably provide goods or services to its competitors without access to the infrastructure or resource; and
> 5. it is economically feasible for the dominant firm to provide its competitors with access to the infrastructure or resource.'[94]

The court found that the complainants failed to fulfil the above requirements in their complaint so as to justify an order compelling the respondents to make available to the complainants the facility in question.

In the case of a developing country like Botswana, *vis a vis* the declaring of patented information of pharmaceutical companies which manufacture aids drugs, it will be very difficult to make use of a similar provision to the South African s8(b) to compel the pharmaceuticals to disclose information as there are no companies [generic drug manufacturers] operating in Botswana who can be said to be competitors of the pharmaceutical companies holding patents to aids drugs. It will, therefore, be very difficult to make the competition laws pertaining to the

[93] *Ibid* see note 86, para [56] at page 31 of the judgment
[94] *Ibid* see note 86, para 57 at pages 31 and 32 of the judgment

*essential facilities* doctrine to work towards making aids drugs available and affordable to the general populace. Issues of capacity constraints here would apply in the same way as they have prevented Botswana and other developing countries to utilize the flexibilities of the WTO TRIPs agreement relating to compulsory licensing.[95]

(iii) *Excessive Pricing to the Detriment of Consumers*

The other prohibited practice which I would like to deal with as arising from the South African case of *Hazel Tau* is that of excessive pricing. The Commission found that GSK and BI were guilty of the prohibited practice of excessive pricing in accordance with s8(a) of the South African Act.[96] This I would like to approach from the angle of how far would a similar provision, in the proposed Botswana legislation, go towards curtailing or controlling the conduct of the pharmaceutical companies from charging exorbitant and unreasonable prices for their medicines. I will attempt to do this by looking at the available decided cases in the EU and South Africa. In her work, Eleanor Fox, a commentator on the area of competition law and policy, addressed the issue of 'abuse of a dominant position' at great length.[97] Just like in South Africa, in the EU, before one can be found guilty of abusive conduct such as excessive pricing, they have to meet the prerequisites of being dominant and pass the market definition test. Section 7 of the South African Act[98] defines what a dominant firm is by referring to a particular market and *market power* which itself is defined at s1 of the Act[99]. Fox cites the case of *Hoffman-La Roche*[100] where the European Court of Justice defined 'dominant position' that is prohibited by article 82 of the EC Treaty in the following terms:

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[95] *Ibid* see note 15
[96] *Ibid* see note 46
[97] Eleanor Fox, Competition Policy, at Chapter 22 of same on 'Abuse of a Dominant Position', available from the 2006 Course Outline for the UCT LLM Competition Law class of Judge D Davis
[98] *Ibid* see note 47
[99] Section 1(1)(xiv) reads –

> '"***market power"*** means the power of a firm to control prices, or to exclude competition or to behave to an appreciable extent independently of its competitors, customers or suppliers; ….'

[100] *Hoffman-La Roche v. Commission,* Case 85/76, [1979] ECR 461

> 'The dominant position … referred to [in article 86 which is now article 82] relates to economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers.'

The similarities with the South African legislation are apparent from the on-set and it would be advisable for Botswana to incorporate similar provisions in her proposed new legislation. The author attempted to break down the court's statement into individual components by stating that a 'dominant position' connotes economic power in a market, power to impose market terms on competitors, or more generally power to hinder the maintenance of effective competition. Fox proceeds to conclude that for legal purposes, dominance may be inferred from a large market share where the next largest firm is half the size of the largest firm or less. In *Hoffman-La Roche*[101], a 47 *per cent* share of the market for Vitamin A was held to be enough to confer dominance in view of the structure of the market (the next largest competitors had 27 *per cent* and 18 *per cent* respectively), Roche's technological lead over its competitors, the absence of potential competition, and Roche's overcapacity. From the above, it is mandatory that there must be a definition of the relevant market for the abuse of dominant position to be proved. In relation to this, Fox points out that if a firm is dominant, it is dominant within a defined market, and as such market definition, that is, the determination of both the product market and the geographic market, must precede a determination of dominance.

From this it is clear that, in the case of the pharmaceutical companies and aids drugs, there will have to be defined a market and the dominance of the firms in that market looking at the share of the market they would have. This is a tedious and expensive process, and in the absence of the requisite structures for investigating, such as the Competition Commission in the case of South Africa, it will be very difficult for Botswana and other developing countries without the necessary capacity to carry out these functions. Thus, as has been

[101] *Ibid* see note 70

suggested in different *fora*, it would be wise for Botswana and other small countries in the region to come together and cooperate on such issues. For example, a proposal can be made to have a trans-national authority within the Southern African Customs Union (SACU)[102], for instance, whose expenses could be shared amongst member states.

In dealing with 'abusive conduct', Fox poses the question: what does it mean to "abuse" a dominant position? In attempting to provide answers to this question, she offers her own interpretation of article 82 of the EC Treaty. She points out that the said provision of the Treaty lists four particular courses of conduct that may be abusive amongst which is conduct that is directly associated with the existence of market power and is often referred to as exploitative in that it represents the use of power over price to extract more than 'fair' or 'competitive' prices from customers. She cites as examples of such conduct, the imposition of unfair prices and limiting production.

(a) Fox then cites two **EU cases** where the allegations of firms having engaged in the abusive conduct of excessive pricing succeeded in the one and failed in the other.

The first is the case of *British Leyland* [103]where British Leyland (BL) was a toll-taker enabled by government license and given the exclusive right to determine whether imported BL cars conformed to UK national standards, and to issue certificates of conformity. BL arbitrarily refused to grant certain certificates to applicants and it set much higher fees for left-hand-drive cars. The court here adopted the test initiated in the earlier case of *General Motors* where the court held that an undertaking abuses its dominant position where it has an administrative monopoly and charges for its services fees which are disproportionate to the economic value of the service provided.

The court in *British Leyland* took into consideration the fact that the verification process did not require an inspection of the vehicle and that it was carried out on the basis of a certificate furnished by a garage. The court was of

[102] The Southern African Customs Union is made up of Botswana, Lesotho, South Africa, Namibia, and Swaziland and was established by agreement of the year 2000
[103] *British Leyland v. Commission* Case 226/84 [1986] ECR 3236

the view that, as such, on the basis of cost incurred, the whole process did not justify the charging of different fees for the issue of certificates of conformity according to whether the vehicles were right-hand-drive or left-hand-drive. The court was of the view that the differences in the fees was solely for the purpose of making the re-importation of left-hand-drive vehicles less attractive. In the circumstances, the court held that the Commission was entitled to conclude that the fee was fixed at a level which was clearly disproportionate to the economic value of the service provided and that the practice constituted an abuse by BL of the monopoly it held by virtue of the British rules. As such, the court held that the complaints made by the Commission in the contested decision were established.

The second case is that of *United Brands*[104] where United Brands was the biggest producer of bananas in the EU. It was a vertically integrated company that grew bananas in South America, bought from other growers half of the bananas it sold, and accounted for some 40 *per cent* of the sales of bananas in the EU, which was more than twice that of its nearest rival. The Commission alleged a series of abuses against United Brands, including the cut-off of a Danish ripener-distributor, excessive pricing and discriminatory pricing. I will confine myself to the findings of the court pertaining to the allegation of excessive pricing. The evidence adduced showed that United Brand's prices were approximately 7 *per cent* higher than the prices of its nearest rivals, and they were 30 *per cent* to 40 *per cent* higher than that of unbranded bananas. The Commission had found discriminatory and excessive pricing violations and ordered United Brands to reduce its prices to distributors other than the distributors for Ireland [where the price was lower by as much as 100 *per cent*] by at least 15 *per cent*.

[104] *United Brands Co. v. Commission* Case 27/76 [1978] ECR 207

> The court stated the test for determining excessive pricing as follows –
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> 'The questions … to be determined are whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competitor products.'[105]

The court acknowledges that the Commission had based its finding that the prices charged by United Brands were excessive on an analysis of the differences between the prices charged in the different member states of the EU and on the policy of discriminatory prices *vis* the low prices charged in Ireland as against the price charged in other member states. The court states that the foundation of the Commission's argument was the letter in which United Brands acknowledged that the margin allowed by the sale of bananas to Irish ripeners was much smaller than in some other EU member states and it concluded from this that the amount by which the actual prices in, for example, Holland, exceeded the delivered Rotterdam prices for bananas to be sold to Irish customers in Dublin must represent a profit of the same order of magnitude.

The court pointed out, nevertheless, that the Commission had not taken into account, in its reasoning, several of United Brands' letters in which were enclosed a confidential document retracting what it had said in its earlier letter and pointing out that the prices charged in Ireland had produced a loss. The court stated that, however unreliable the particulars supplied by United Brands in subsequent letters may be, the onus of proving that United Brands had charged excessively remained with the Commission. The court was of the view, further, that the Commission had not effectively refuted United Brands' retraction which all established doubt that the basis for the calculation adopted by the Commission to prove that United Brands' prices were excessive is open to criticism, and that on this particular point there was doubt which must benefit United Brands, especially [in the eyes of the court] as for nearly 20 years banana prices had, in real terms, not risen on the relevant market.

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[105] *Ibid* see note 104, at para 252

In the circumstances, the court held that the Commission had not adduced adequate legal proof of the facts and evaluations which formed the gravamen of its finding that United Brands had infringed article 86 [now article 82] of the Treaty by directly and indirectly imposing unfair selling prices for bananas.

It is clear from the two cases that in the case of Botswana and the pharmaceutical companies manufacturing aids drugs, at a time when competition legislation is in place, where one alleges excessive and unfair pricing by the pharmaceutical companies, they would have to satisfy the test indicated in the two cases. This would be a tedious and expensive exercise which would require the authorities to be equipped with capacity both in the form of economic expertise and financial resources to enable it to carry out the requisite investigations. This being so in that they would have to show that the pharmaceutical companies are charging prices which are disproportionate to the economic value their product as per *British Leyland*[106], or that looking at the costs of production incurred by the companies, the profits they are making are excessive and that the price is in itself unfair or as compared to competitor products as per *United Brands*[107].

Reyburn[108] is of the further view that cost-price and profitability should not be made in isolation and that an examination of other characteristics of the market may provide a reasonable explanation of the high price. He cites here that in an instance where a firm engages in activities with significant *ex ante* risks or investment in research and development, the difference between price and unit cost of production may reflect the up-front investment and the comparative rewards of innovation. However, he goes on to state, in quoting *Napp Pharmaceuticals*,[109] that *ex ante* investment is not a reasonable justification where such investment has long been recouped, and that the argument that a firm should be allowed supra-normal profits on one product to fund research and development on risky new products has been rejected in at

[106] *Ibid* see note 103
[107] *Ibid* see note 104
[108] *Ibid* see note 38 at 7-37
[109] *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading UK Competition Appeal Tribunal 2002-01-15* Case No 1001/1/1/01 at paras 407, 416-418

least one case.[110]

All this will entail the Commission knowing the prices charged by the companies and those of their competitors [being the manufacturers of generic drugs], and also the costs of production which can only be obtained from the companies upon the court requesting disclosure from them of such things as balance sheets and other confidential documents. The earlier argument about cooperation applies here, and Botswana would do well to learn from other countries where the area of competition law is more developed [such as South Africa] and seek assistance in the form of technology transfer and training on the workings of competition authorities. As such, this would present a great opportunity to deal with those companies seeking to maximise profits by exploiting consumers and abusing their dominant position in the relevant market.

(b) Fox states that **US antitrust law** does not prohibit excessive pricing and that it prohibits price discrimination but only if the discriminatory pricing is likely to produce monopoly or hurt disfavoured buyers in their competition with favoured ones. This is not the example for Botswana to follow in her competition law as [I think] the US model is better suited to developed economies such as theirs where free enterprise is the order of the day. If Botswana were to follow the US example, it would lead to a situation where in the case of the pharmaceutical companies and aids drugs, the companies would be given a free hand in determining prices with no checks and balances in place to regulate them. I think this explains why, as Fox points out, virtually all the post-communist, newly free-enterprise economies adopt the EC model and not the US model.

[110] *Ibid* see note 109 at para 413

Fox states that the US position on excessive pricing was underscored by the Court of Appeals for the Second Circuit in *Berkey/Kodak*[111] where the court stated the following:

> 'Excessive prices, maintained through exercise of a monopolist's control of the market, constituted one of the primary evils that the Sherman Act was intended to correct …
>
> But unless the monopoly has bolstered its power by wrongful actions, it will not be required to pay damages merely because its prices may later be found excessive. Setting a high price may be a use of monopoly power, but it is not in itself anticompetitive. Indeed, although a monopolist may be expected to charge a somewhat higher price than would prevail in a competitive market, there is probably no better way to guarantee that its dominance will be challenged than by greedily extracting the highest price it can … judicial oversight of pricing policies would place the courts in a role akin to that of a public regulatory commission ….
>
> We would be wise to decline that function unless Congress clearly bestows it upon us.'[112]

Notwithstanding the above, Fox avers that legislators and enforcement agencies in the US do react when private firms have enormous power and exploit the public. The author cites as an example, where in the wake of the 1990 oil shock, the state of Pennsylvania passed excessive pricing laws; the National Association of [State] Attorneys General developed a plan to support anti-price gouging legislation; and the Department of Justice opened an investigation to determine whether the sudden sharp increases in the price of gasoline were collusive. She also mentions that the exorbitant prices of aids drugs have led to what she terms 'public uproar, jawboning, and "voluntary" price reductions'. But one may argue that this does not have the force of law and as such a more permanent and compelling mechanism has to be in place *a la* the EC Treaty provisions on excessive pricing.

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[111] *Berkey Photo Inc. v Eastmen Kodak Co.,* 603 F. 2d 263, 294 (2d Cir.1979), cert. denied, 444 U.S. 1093, 100 S.Ct. 1061, 62 L.Ed.2d 783 (1980)

[112] *Ibid* see note 111

(c) The **position currently in South Africa** is that there is no case law on excessive pricing and in *Glaxo Wellcome,*[113] the one case in which a ruling could have been made on the issue, it was struck out for procedural irregularity after preliminary arguments were raised thus preventing the court from dealing with the merits relating to the allegation of a breach of s8(a) of the Act dealing with excessive pricing.

However, there seems to be light at the end of the tunnel in that the case of *Sasol v Omnia Fertilizer Ltd*[114] might just present the court with the opportunity to make a ruling on the issue of excessive pricing. In this case the complainant (Omnia) had submitted a complaint to the Commission alleging, *inter alia*, that Sasol had violated s8(a) of the Act in that its prices were excessive. At first, the Commission decided not to refer the matter to the Tribunal citing a lack of sufficient evidence to back up the complaint. Instead of proceeding on its own to the Tribunal based on the non-referral by the Commission, the complainant chose rather to go and gather new facts which were more extensive and dealt in part with events that had occurred after the filing of the first complaint. The Commission investigated this new complaint and referred it to the Tribunal. Sasol sought to challenge the validity of this referral of the new complaint arguing that the Commission had previously rejected the complaint and as such was *functus officio*, at the same time seeking to plead *res judicata* in that the matter had been dealt with. The court held that there are no provisions in the Act preventing the Commission from reconsidering a prior decision unless it does so for an ulterior motive. These had not been pleaded by Sasol, and the court had no reason to find that the Commission had acted out of an ulterior motive in referring the second complaint to the Tribunal. The court held, further, that if new facts are placed before the Commission or if new facts come to light which were not previously known to the Commission, it is enjoined to investigate the complaint in order to properly fulfil its statutory function as the primary body responsible for prosecuting any conduct which is alleged to be

[113] *Ibid* see note 86
[114] *Sasol Chemical Industries v Competition Commission, Omnia Fertilizer Limited and Others* Case 52/CAC/Jun 05; judgment delivered on 28 April 2006

prohibited by the Act. The court stated that there are two circumstances where the Commission would be precluded from making a referral *vis* where the issue had previously been determined by the Tribunal or where in consequence of the Commission's refusal to prosecute a complaint, the complainant itself is prosecuting the complaint. Neither of these applied to the present case and as such the court dismissed Sasol's applications.

With the technical issues out of the way it is hoped that the court will proceed to hear the arguments on the merits and make a ruling on the issue of excessive pricing, in the process setting a precedent of South African case law. [I submit, however, that all efforts to find out how far the case was and if the complainant had decided to go all the way to court for the determination of the allegations it has levelled against Sasol proved futile]

Reyburn throws in his bit by stating that the South African prohibition of excessive pricing at s8(a) follows the more regulatory approach of the EC. He, however, says that the application of the provision is quite difficult where he says the following:

> '…[b]ut even in the EC, aside from a series of cases in the area of telecommunications, dominant firms have not been commonly charged with, or found liable for, excessive pricing. This may be explained in part by the difficulty of determining when a price is excessive and an understandable reticence on the part of competition authorities to become price regulators.'[115]

Thus, any complainant in Botswana would have their work cut out in trying to prove prohibited conduct by the pharmaceutical companies pursuant to the provision in the proposed Botswana legislation, that would be the equivalent of the South African s8(a) on excessive pricing.

The author goes on to raise an important point that the South African courts and commentators have thus far referred to excessive pricing as a '*per se* offence'. He says that the above is not true and can be misleading, in so far as it seeks to portray the view that a complainant under s8(a) of the South African

[115] *Ibid* see note 38, at 7-36

Act need not prove that the excessive pricing conduct has some detrimental effect on consumers. He says that the correct position is that the complainant must prove that the conduct has an effect and the nature of the effect is specifically that the pricing must be to 'the detriment of consumers'. This phrase or concept, the author concedes, is a peculiarly South African invention which has no equivalent in EC law. This further requirement would serve only to increase the burden on a complainant in Botswana *vis-à-vis* proving excessive pricing conduct, therefore, making it even more difficult to prove. As such, a lot of time must go into deciding whether, on this point, the proposed Botswana legislation follows the EC or the South African example.

**CONCLUSION**

This paper has demonstrated the lengths that both the WTO multilateral trading system and competition law and policy can go in delivering AIDS drugs to the people in developing countries, and their shortcomings. I would like, in closing, to make the following few points:

(a) the Director-General of the WTO [Pascal Lamy] feels that the agreed amendment of the TRIPS Agreement is the ideal way forward as it confirms the members' determination to ensure that the system contributes to the humanitarian and development goals of the organisation;

(b) on the same victory trail, Amina Mohamad [Kenyan Ambassador and Chair of the WTO General Council] says that the benefits of the amendment is to ensure that African nations and the rest of the developing world have access to affordable medicines and that they are able to drive the price of drugs to even lower levels;

[The above views seem to suggest a high confidence in the eventual working of the system and call for a bit more patience with the system so that we can see the fruits later on]

(c) those who harbour a contrary view to the 'victory' celebrations, such as Ellen 't Hoen [the coordinator of one of the projects for Medicines without Frontiers], feel that until the good that is on paper is transformed into tangible success that will deliver medicines to the people, there is no cause for celebration;

(d) there are also those who feel that for the system to work and benefit developing countries, diplomatic efforts must be taken to ensure that countries such as the US desist from using economic threats to exert pressure on developing countries to refrain from using the flexibilities in the TRIPS Agreement to issue compulsory licenses over patented medicines. They cite the example of FTAs which the US seeks to conclude with many developing countries, and which impose stringent TRIPS-plus requirements on the smaller countries;

(e) a recommendation was made earlier by Adede *supra* where he said that African countries should look into passing appropriate national legislation that will enable them to take advantage of compulsory licensing or parallel importation, together with antitrust laws that would ensure that the competitive process is preserved;

(f) there has also been a call for there to be lee-way for allowing competition authorities to act in the preservation of life as a matter of public policy so as to justify the competition authorities interfering with patent-owners rights in appropriate circumstances;

(g) regarding the 'essential facility' doctrine, EU law has left the door open that intellectual property can constitute an essential facility such that one may be ordered, by a court, to make such facility available to his competitors;

(h) in coming up with competition legislation, it would be wise for Botswana and other developing countries to adopt the more regulatory model of the EU and South Africa, unlike the US which has left a lot to the whims of the courts; and

(i) for the sound implementation of competition legislation there has to be structures [in the form of authorities like the Commission, the Tribunal, and the Competition Appeals Court as in South Africa] in place. On this note, Botswana can learn from South Africa and other countries and try to tailor her system in accordance with her resources and objectives. Also, Botswana can seek cooperation with other developing countries in the region to coordinate the functioning of competition authorities and to jointly finance same.

All in all, I submit that a balance should be struck between competition law and the multilateral trading system of the WTO in attempting to make medicines available to people in the developing world at affordable prices.

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