

**Evaluation of the
Essential Facilities and Exclusionary Acts**

**Prepared by
The Consumer Project on Technology**

**Report to
The Competition Commission,
Republic of South Africa**

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In the Matters of:

Hazel Tau et al.

v.

GlaxoSmithKline, Boehringer Ingelheim, et al.

&

Aids Healthcare Foundation et al

v.

GlaxoSmithKline, Boehringer Ingelheim, et al.

Case Numbers: 2002sep226 & 2002jan357

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ACRONYMS

3TC	Lamivudine, brand name Epivir
ABC	Abacavir, brand name Ziagen
AIDS	Acquired Immune Deficiency Syndrome
API	Active Pharmaceutical Ingredient
ARV	Antiretroviral Medicine
ATC	Anatomical Therapeutic Classification
AZT	Zidovudine, brand name Retrovir
AZT+3TC	Zidovudine and Lamivudine, brand name Combivir
AZT+3TC+ABC	Zidovudine, Lamivudine, and Abacavir, brand name Trizivir
BI	Boehringer Ingelheim (Pty) Ltd, Ingelheim Pharmaceuticals (Pty) Ltd and Boehringer Ingelheim GmbH and Related Companies
CPTech	Consumer Project on Technology
d4T	Stavudine, brand name Zerit
ddI	Didanosine, brand name Videx
EC	European Community
ECJ	European Court of Justice
EFZ	Efavirenz, brand name Stocrin
ESCR	United Nations Economic, Social, and Cultural Rights Committee
FDC	Fixed Dose Combination
FTC	Federal Trade Commission
GSK	GlaxoSmithKline South Africa (Pty) Ltd, Glaxo Group Limited and Related Companies
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
ICESCR	International Covenant on Economic, Social, and Cultural Rights
ISO	Independent Service Organisation
MCC	Medicine Control Council
MSF	Médecins Sans Frontières
NNRTI	Non-nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Analogue Reverse Transcriptase Inhibitor

REDACTED VERSION

NVP	Nevirapine, brand name Viramune
PI	Protease Inhibitor
R&D	Research and Development
RTPC	Restrictive Trade Practices Commission
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property
WHO	World Health Organisation
WTO	World Trade Organization

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SECTION 1: INTRODUCTION

In September 2002, the Competition Commission of the Republic of South Africa received a complaint from Hazel Tau and others alleging that GlaxoSmithKline and Boehringer Ingelheim, and their South African subsidiaries, were engaged in conduct prohibited by the Competition Act. Specifically, it was alleged that the respondents had charged, and were still charging, excessive prices to the detriment of consumers for patented antiretroviral medicines needed to treat HIV/AIDS.

The Competition Commission contracted with the Consumer Project on Technology (CPTech) to assist with the investigation of the matter. Specifically, the Commission requested CPTech to prepare an expert report dealing with the following matters:

- Whether the Respondents have refused to give their competitors access to an essential facility when it was and is economically feasible to do so in contravention of section 8(b) of the Act.
- Whether the Respondents have engaged in exclusionary conduct, the anti-competitive effect of which outweighs its technological, efficiency or other pro-competitive gain, in contravention of section 8(c) of the Act.

This report concludes that the respondents have contravened the Competition Act of 1998 by abusing their dominant positions in markets for medicines needed to treat AIDS.

As of July 2003, respondents priced their patented products five to fifteen times higher than generic equivalents and about twice as high as the median household income in South Africa. Until this time, they refused to grant licences for their patents to consumers or generic suppliers in exchange for reasonable royalty payments. As a result, hundreds of thousands of people with AIDS in South Africa cannot afford the medicine they need to survive.

The respondents' refusals to grant licences to qualified generic suppliers is in contravention of section 8(b), which states that it is prohibited for a dominant firm to "refuse to give a competitor access to an essential facility when it is economically feasible to do so". It is economically feasible for the respondents to grant licences for their patents in return for reasonable royalty payments.

The respondents' refusals to licence their patents also contravenes section 8(c) of the Act, which states that it is prohibited for a dominant firm to "engage in an exclusionary act . . . if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain". The dramatic increases in morbidity and mortality from lack of access to affordable generic medicines far outweighs any incentives to innovate or other procompetitive effects of the respondents' practices. The respondents' refusals to licence their patents is contrary to the purposes of the Competition Act, which include promoting development, furthering equity, providing consumers with competitive prices and product choices, advancing social and economic welfare and correcting structural imbalances in the economy.

Section two of the report surveys the factual background of the case, including the state of the AIDS crisis in South Africa, the need for the respondents' medications, and how the respondents have inhibited access to them through their refusals to grant licenses to lower-cost suppliers. Section three surveys the legal context relevant to interpretation of the Competition Act, including constitutional and human rights standards, international trade obligations, comparative law and the jurisprudence developed by South African courts. Section four proposes generally-applicable standards for interpreting the Competition Act's mandates in cases involving access to intellectual property. Section five applies these standards to the respondents' practices. Section six concludes with recommendations for remedial orders, including for a compulsory open licence to authorise competition in the supply of the respondents' medicines and a monetary penalty for each year that the respondents have been in violation of the Act's mandates.

SECTION 2: BACKGROUND

2.1 THE RESPONDENTS AND THEIR ARV PATENTS

The respondents are GlaxoSmithKline South Africa (Pty) Ltd, Glaxo Group Limited and Related Companies (referred to collectively as GSK) and Boehringer Ingelheim (Pty) Ltd, Ingelheim Pharmaceuticals (Pty) Ltd and Boehringer Ingelheim GmbH and Related Companies (referred to collectively as BI).

GSK and BI hold patents on certain antiretroviral (ARV) medications used to treat acquired immunodeficiency syndrome (AIDS). GSK holds patents in South Africa on zidovudine (AZT), sold under the brand name Retrovir, lamivudine (3TC), sold under the brand name Epivir, and AZT+3TC, sold under the brand name Combivir. BI holds patents in South Africa on Nevirapine (NVP), sold under the brand name Viramune.

2.2 THE AIDS EPIDEMIC IN SOUTH AFRICA

“The scale of the AIDS crisis now outstrips even the worst-case scenarios of a decade ago.”

-Joint United Nations Programme on HIV/AIDS (2002)

In 2000, human immunodeficiency virus (HIV), and the acquired immunodeficiency syndrome (AIDS) that it causes¹, overtook tuberculosis as the world’s leading infectious cause of adult death.² AIDS is the most devastating communicable cause of death since the 14th Century bubonic plague.³

As Table 1 depicts, by the end of 2002, there were an estimated 42 million people in the world living with HIV infection, 95 percent of whom live in developing countries.⁴ Sub-Saharan Africa accounts for 70 percent of the world’s population of people living with HIV/AIDS, 70 percent of new infections, and 77 percent of AIDS-related deaths.⁵

South Africa has been particularly hard hit by the AIDS epidemic. According to UNAIDS estimates, South Africa has the highest population of people with AIDS of any country in the world. It alone accounts for 12 percent of the world’s people living with HIV/AIDS (see Table 1). As the founding complaint by Hazel Tau et al. records, “AIDS is now the leading

¹ A concise definition of AIDS was provided by the US Federal Circuit in *Burroughs Wellcome Co. v. Barr Laboratories*, 40 F.3d 1223, 1225 (Fed Cir 1994):

The disease attacks and destroys certain white blood cells known as CD4 T-lymphocytes or T-cells, which form an important component of the body’s immune system. The level of destruction eventually becomes so great that the immune system is no longer able to mount an effective response to infections that pose little threat to a healthy person.

² L Garrett, *Of epidemic proportions/UN report: AIDS deaths to surpass plague, Spanish flu*, *Newsday* A8 (29 Nov 2000).

³ *Id.*; see also Statement of UN Secretary-General Kofi Annan, United Nations General Assembly Special Session on HIV/AIDS (June 2001) (describing AIDS as “the greatest threat to global health since the Black Death of the 14th century”).

⁴ UNAIDS, *AIDS Epidemic Update* (December 2002).

⁵ *Id.*

cause of mortality in South Africa” with between 200,000-360,000 people estimated to die of the disease each year.⁶

Table 1: Regional HIV AIDS Statistics, 2002

Region	Adults and Children living with HIV/AIDS	Adults and Children newly infected with HIV	Adult prevalence rate ⁷	Estimated Number of Adult and Child Deaths Due to HIV/AIDS
Sub-Saharan Africa	29,4 million	3,5 million	8,8 %	2,400,000
South & South East Asia	6,0 million	700,000	0,6 %	440,000
SOUTH AFRICA ⁸	5,0 million	N/A	20,1 %	360,000
Latin America	1,5 million	150,000	0,6 %	60,000
East Asia & Pacific	1,2 million	270,000	0,1 %	45,000
Eastern Europe & Central Asia	1,2 million	250,000	0,6 %	25,000
North America	980,000	45,000	0,6 %	15,000
Western Europe	570,000	30,000	0,3 %	8,000
Caribbean	440,000	60,000	2,4 %	42,000
North Africa & Middle East	55,000	83,000	0,3 %	37,000
Australia & New Zealand	15,000	500	0,1 %	<100
TOTAL	42 million	5 million	1,2 %	3,100,000

Source: UNAIDS, *AIDS Epidemic Update, 2002* pages 38-41; UNAIDS *Epidemiological Fact Sheets on HIV/AIDS and Sexually Transmitted Infections, South Africa, 2002 Update*, pg. 2

The Joint Health and Treasury Task Team charged with examining treatment options in the public sector in South Africa states that there are approximately 4,7 million South Africans infected with the HIV virus and between 400,000 and 500,000 with “clinical AIDS.”⁹ The estimate of the number with clinical AIDS corresponds to other estimates of the number of people in South Africa with “full blown” or “stage 4” AIDS, meaning that without access to antiretroviral therapy they will die in 12 to 18 months.¹⁰

⁶ Statement of Complaint Submitted by Hazel Tau, et al., para 20 (citing Report by the Medical Research Council, Annexure C to the complaint); UNAIDS, *AIDS Epidemic Update* (December 2002).

⁷ The proportion of adults (15 to 49 year of age) living with HIV/AIDS in 2002.

⁸ South Africa estimates are from UNAIDS *Epidemiological Fact Sheets on HIV/AIDS and Sexually Transmitted Infections, 2002 Update*. These estimates are for end of year 2001.

⁹ *Summary Report of the Joint Health and Treasury Task Team Charged with Examining Treatment Options to Supplement Comprehensive Care for HIV/AIDS in the Public Sector* (1 August 2003); see also *12th National HIV and Syphilis Seroprevalence Survey in SA*, National Department of Health (2001) (estimating that there are approximately 4.74 million South Africans living with HIV/AIDS).

¹⁰ See Rob Dorrington et al., *HIV/AIDS Profile in the Provinces of South Africa*, (2002) THE CENTRE FOR ACTUARIAL RESEARCH, MEDICAL RESEARCH COUNCIL, & THE ACTUARIAL SOCIETY OF SOUTH AFRICA 6 (estimating that 407,000 people in South Africa are in stage four). Stage four is the final stage of AIDS. In stages one and two, patients test positive for HIV virus but are relatively asymptomatic. In stage three, patients suffer from weight loss and increased episodes of opportunistic infections as the immune system weakens. Many people in stage three are recommended for ARV treatment. In stage four, HIV infection is considered ‘full-blown’ AIDS disease. Patients in stage four are frequently bed ridden, have severely diminished immune

The toll exacted by AIDS on South African society is immense. The complaint in this case accurately records that:

The MRC report estimates that about 40% of adult deaths aged 15-49 in 2000 were due to HIV/AIDS, and that about 20% of all adult deaths in that year were AIDS-related. . . . Without appropriate treatment to prevent and/or delay the onset of AIDS in people living with HIV, the MRC forecasts that “the number of AIDS deaths can be expected to grow, within the next 10 years to more than double the number of deaths due to all other causes, resulting in 5-7 million cumulative AIDS deaths in South Africa by 2010”.¹¹

AIDS does not affect all segments of the population equally. The government’s latest report notes the growing “appreciation of the importance of social conditions and particularly poverty, both in undermining the immune system in general and in increasing susceptibility to HIV infection as well as progression to AIDS”.¹² In South Africa, extensive surveys have shown that those infected with the HIV virus are disproportionately young adults who are poor, female and African.¹³ Given the 61 percent absolute poverty rate in the African community, the Joint Health and Treasury Task Team appears reasonable in its conclusion that “50% of people with AIDS may have inadequate access to food.”¹⁴

2.3 ANTIRETROVIRAL THERAPY

Less than a decade ago, someone living with HIV/AIDS had little hope. HIV infection brought a steady, inexorable decline towards the complete destruction of the immune system and death. The introduction of ARVs in 1996 was a turning point for hundreds of thousands of people with access to sophisticated health care systems. . . . [T]oday we are again at a turning point – this time in favour of the developing world.
-World Health Organisation¹⁵

Although there is no cure for AIDS, the majority of AIDS deaths in any given year can be avoided with proper medication. Since 1996, combinations of ARV medicines into treatment

systems, experience frequent opportunistic infections and are highly likely to die from an AIDS-related complication within one year.

¹¹ Statement of Complaint Submitted by Hazel Tau, et al., paras 20-21; *see also* Annexure C to the founding complaint.

¹² *Summary Report of the Joint Health and Treasury Task Team Charged with Examining Treatment Options to Supplement Comprehensive Care for HIV/AIDS in the Public Sector* at 4 (1 August 2003)

¹³ *See* NELSON MANDELA/HSRC REPORT ON HIV/AIDS IN SOUTH AFRICA (2002); Rob Dorrington et al., *HIV/AIDS Profile In The Provinces Of South Africa*, THE CENTRE FOR ACTUARIAL RESEARCH, MEDICAL RESEARCH COUNCIL, & THE ACTUARIAL SOCIETY OF SOUTH AFRICA 4 (2002). These surveys show that among youth aged 15-24 years, there are approximately four infected young women for every infected young man (21,6 % and 5,8 % respectively) and Africans have approximately twice the HIV prevalence rates of Whites and Coloureds and eight times that of Indians/Asians.

¹⁴ *Summary Report of the Joint Health and Treasury Task Team Charged with Examining Treatment Options to Supplement Comprehensive Care for HIV/AIDS in the Public Sector* 14 (1 August 2003)

¹⁵ World Health Organisation, *SCALING UP ANTIRETROVIRAL THERAPY IN RESOURCE-LIMITED SETTINGS: GUIDELINES FOR A PUBLIC HEALTH APPROACH*, 8-9 (2002), available at <http://www.who.int> (referred to hereinafter as “SCALING UP”).

regimes now known as highly active antiretroviral therapy (HAART) have enabled countries to cut overall deaths from AIDS by as much as 70 percent.¹⁶

The effectiveness of HAART, including in developing countries, has been confirmed by the World Health Organisation (WHO). According to the WHO, HAART can lead to “immunological restoration, a slowing of disease progression, durable therapeutic responses, improvements in the quality of life, and prevention of drug resistance”.¹⁷ These “reductions in morbidity and mortality resulting from the introduction of [HAART] have been confirmed in all settings in which it has been used, including developing countries, e.g. Brazil, Senegal, Thailand, and Uganda.”¹⁸ In April 2002, the WHO added a broad list of ARVs to its Model List of Essential Drugs that “should . . . be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford.”¹⁹

The benefits of HAART have been established in South Africa.²⁰ Dr. Robin Wood, Principal Medical Specialist for the Provincial Administration of the Western Cape and Director of the HIV Research Unit at Somerset Hospital, reports that in his clinical experience “use of HAART [in South Africa] has decreased the incidence of HIV-Associated TB by 81%, hospitalization by 80% and deaths by 94%.”²¹ Dr. Eric Goemaere, Head of Mission for Médecins Sans Frontières (MSF) South Africa, noted the experience of the HIV/AIDS clinics run by MSF in Khayelitsha Township (Cape Town) in which “a two pill regimen of zidovudine, lamivudine and nevirapine taken twice a day, has achieved viral suppression in 90% of the patients after three months of HAART.”²²

The potential benefits from universal access to HAART in South Africa are enormous. The Joint Health and Treasury Task Team reports that providing treatment to 100 percent of the people who need it in South Africa “would see 1.2 million people in treatment by 2008” and would yield 1.7 million deaths deferred; 9.3 million years of life gained and 860,000 orphans deferred.²³

¹⁶ See Centers for Disease Control and Prevention, *HIV/AIDS Surveillance Report 2001*; Joint United Nations Programme on HIV/AIDS, *Report on the Global HIV/AIDS Epidemic 2002* 10 (2002), available at <http://www.unaids.org/barcelona/presskit/report.html>

¹⁷ SCALING UP at 24. The WHO records other benefits as well:

“The provision of antiretroviral treatment can reinforce effective prevention campaigns, stimulate voluntary counselling and testing and help to destigmatize HIV infection. Furthermore, antiretroviral drugs have proved highly effective in preventing mother-to-child transmission (MTCT) of HIV and have the potential to decrease sexual transmission in the general population.”

SCALING UP at 22.

¹⁸ *Id.*

¹⁹ WHO Expert Committee on Essential Drugs (Nov. 1999) (describing purpose of essential drug list); see SCALING UP at 27 (explaining addition of ARVs to model list).

²⁰ *Summary Report of the Joint Health and Treasury Task Team Charged with Examining Treatment Options to Supplement Comprehensive Care for HIV/AIDS in the Public Sector* 9 (1 August 2003) (“Antiretroviral therapy has been demonstrated to significantly extend life, reduce mortality, and improve health status in people in Stage 3 and 4 of HIV disease.”).

²¹ Expert Affidavit of Dr. Robin Wood, Expert Annexure RW, para 10 (citations omitted).

²² See Letter from Dr. Eric Goemaere to the Competition Commission (31 July 2003); Expert Report of Brook Baker; Expert Affidavit of Robin Wood, Annexure RW to Complaint.

²³ *Summary Report of the Joint Health and Treasury Task Team Charged with Examining Treatment Options to Supplement Comprehensive Care for HIV/AIDS in the Public Sector* 18 (1 August 2003); see *id.* at 9 (explaining that “the point at which the individual develops an ‘AIDS-defining illness’” is when “the role of antiretroviral drugs becomes important”).

2.3.1 The Necessity of Combination Therapy

Dr. Eric Goemaere, Head of Mission for MSF South Africa, explains in his 31 July 2003 letter to the Commission:

WHO and all international guidelines for implementation of highly-active antiretroviral therapy (HAART) agree that in order to achieve sustained viral suppression in the treatment of HIV, it is necessary to (1) use a combination therapy of at least three different antiretroviral agents from at least two different classes of drug with additive or synergistic antiviral activity, and (2) assure good adherence to treatment regimens.

A three-drug HAART regime, sometimes called a “cocktail,” consists of a “backbone” of two nucleoside analogue reverse transcriptase inhibitors (NRTIs)²⁴ plus a third powerful drug such as a non-nucleoside reverse transcriptase inhibitor (NNRTI)²⁵ or a protease inhibitor (PI). Different patients require different combination therapies and medicines depending on a host of factors including age of the patient, potential side effects, pregnancy, interactions with other drugs and interaction of drugs with different illnesses.²⁶ Many patients also develop tolerance to the first regime of ARVs administered, necessitating access to a “second-line” of treatment with a completely new set of drugs. For these reasons, the WHO advises that HAART in developing countries be standardised and that “countries select a single first-line regime and a limited number of second-line regimes for large-scale use, while recognizing that persons who cannot tolerate or who fail the first-line and second-line regimes would be referred for individualized care by specialist physicians.”²⁷

Both Dr. Wood and Dr. Goemaere state in their expert opinions that effective treatment of AIDS in South Africa requires access to all three of the medicines that are subject to the complaint in this case: AZT, 3TC and NVP. With regard to the necessity of access to AZT and 3TC, Dr. Robin Wood describes the accepted international practice as reflected in the WHO’s guidelines:

AZT and [3TC] are listed as the initial recommendation for the dual NRTI component based on efficacy, toxicity and clinical experience, as well as the availability of the medicines in a fixed dose combination. Other NRTIs may be substituted for the AZT/[3TC] dual NRTI component in first-line regimens. However, AZT/[3TC] would then be required as potential components for second line regimens.²⁸

Dr. Wood additionally notes the necessity of access to NVP because NNRTI regimens (such as AZT+3TC+NVP) have advantages over PI-based regimes for the first-line treatment, including that “the regimen is potent and the drugs are available at reasonable pill counts.”²⁹ Dr. Wood further notes that NVP has therapeutic advantages for some patients over efavirenz (EFZ), the alternative drug in the NNRTI class. These include that “the potential teratogenic

²⁴ WHO recommended NRTIs include: zidovudine (AZT), lamivudine (3TC), abacavir (ABC), stavudine (d4T) or didanosine (ddI).

²⁵ WHO recommended NNRTIs include: nevirapine (NVP) and efavirenz (EFZ).

²⁶ See Expert Affidavit of Robin Wood, Annexure RW to Complaint paras 22-41.

²⁷ SCALING UP, at 11.

²⁸ Expert Affidavit of Robin Wood, Annexure RW to Complaint para 24.

²⁹ Expert Affidavit of Robin Wood, Annexure RW to Complaint para 25.

effects of efavirenz preclude its use in pregnant women or women of childbearing age who are at risk of falling pregnant.”³⁰ It is additionally noteworthy that, as described below, EFZ is not yet available in any two or three-drug fixed dose combination.

Summarising this evidence, Dr. Wood concludes that in his expert opinion:

ARVs, even within the same therapeutic class, cannot be considered as fully substitutable for each other. Because of the matrix of interconnected factors relating to toxicity and effectiveness of treatment, access to a wide choice of ARVs is required in order to effectively administer HAART.³¹

Dr. Goemaere reviews similar evidence on treatment needs in his submission from MSF. He concludes: “The unavailability of either zidovudine, lamivudine or nevirapine, removes the possibility of constructing two three-drug regimens for the majority of those who require them.”

The views of Drs. Wood and Goemaere are in accord with those of the WHO. As Dr. Wood notes in his submission, in deciding to place a broad list of ARVs on the Model List the WHO Expert Committee on the Selection and Use of Essential Medicines stated:

While accepting that there were many circumstances in medicine where one essential drug may substitute easily for other members of a class, thus allowing the placement of a single agent on the Model List (with appropriate advice about substitution), this was not possible with HIV treatment. Effective therapy requires commencement of three drugs simultaneously, and alternative regimens are necessary to meet specific requirements at start-up, to substitute for first-line regimens in the case of toxicity, or to replace failing regimens. The committee considered various approaches to the listing of these agents but agreed finally that if they were to be listed, all drugs recommended should be included in the Model List.³²

2.3.2 The Importance of Fixed Dose Combinations

The expert reports submitted in this case make clear that access to fixed dose combinations (FDCs) are needed to lower pill counts and increase adherence to treatment regimes, which in turn decrease the incidence of resistance of the AIDS virus to ARV treatment.³³ Dr. Eric Goemaere, explains in his 31 July 2003 letter to the Commission:

Treatment of AIDS with HAART requires good levels of adherence to achieve sustained viral suppression. Some experts argue that a rate of 80% adherence is needed to ensure, to the extent possible, treatment success and to avoid the onset of resistant strains of HIV. FDCs are important for the simplification of treatment

³⁰ Expert Affidavit of Robin Wood, Annexure RW to Complaint para 25.

³¹ Expert Affidavit of Robin Wood, Annexure RW to Complaint, para 43. *See also* para 28 (“There is no single ARV regimen which will be ideal for either all patients or for all clinical situations. Therefore, it is necessary to have access to a combination of drug choices both within and between drug classes.”).

³² *12th Expert Committee on the Selection and Use of Essential Medicines Meeting, 15-19 April 2002*, Annexure F to Statement of Complaint.

³³ *See* Letter from Dr. Eric Goemaere to the Competition Commission (31 July 2003); Expert Report of Brook Baker; Expert Affidavit of Robin Wood, Annexure RW to Complaint.

regimens and the reduction of pill burdens. There is countless evidence documenting the benefits of simplified regimens in terms of maximising adherence to therapies indicated for chronic conditions in general. In the case of AIDS treatment, numerous studies in countries where HAART has been available since its advent have demonstrated that a low burden of pills and a low frequency of daily dosages dramatically improve adherence.

In addition to the fact that low pill burdens improve adherence to the entire regimen overall, a further advantage of FDCs is that they minimise the risk of patients taking only part of their treatment. This can often be motivated by patients' avoidance of those drugs that cause them adverse events, as well as patients' unwillingness to take many pills. These lessons have been learned numerous times from the implementation of tuberculosis programs. Failure to take all three antiretrovirals continuously rapidly results in treatment failure and virological resistance. FDCs are particularly effective in guarding against errors in how treatment is taken, and prevent these problems.³⁴

The WHO Guidelines similarly recommend “the development of innovative strategies for enhancing adherence to ART because of its lifelong nature Such strategies include minimizing pill counts and dosage frequencies by preferentially using combination pills on a once-daily or twice-daily basis.”³⁵

There are few three-drug FDCs; two-drug FDCs are more common. Of the three-drug FDCs that are available, only NVP and abacavir (ABC) are the third drug in currently available three-drug FDCs. NVP, as the third drug, is available from generic manufacturers with either AZT+3TC or d4T+3TC as the backbone. ABC is available in the only FDC from a brand manufacturer: AZT+3TC+ABC (Trizivir) by GSK. However, Trizivir is “not highly recommended clinically.”³⁶

2.4 AFFORDABILITY BARRIERS

Despite widespread recognition of the benefits of HAART, access to ARV medicines in developing countries is severely lacking, as represented in Figure 1 below.³⁷ In South Africa, it is estimated that 400,000 to 500,000 people are in immediate need of HAART, but less than 30,000 people with AIDS receive the treatment they need.

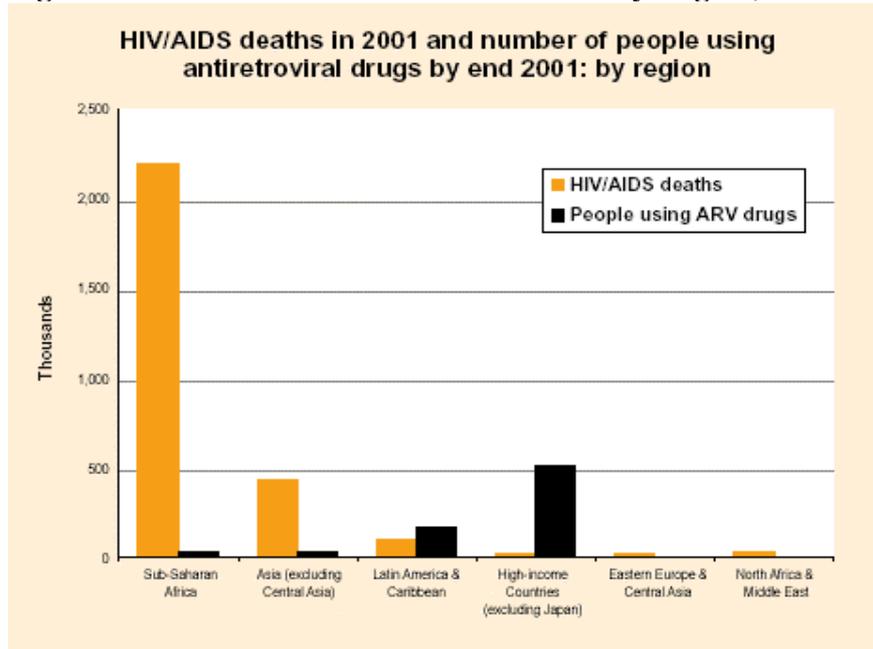
³⁴ Letter from Dr. Eric Goemaere, Head of Mission, MSF South Africa to Mr. Thulani Kunene, Senior Investigator: Enforcement and Exemptions, South African Competition Commission 8 (July 31, 2003).

³⁵ SCALING UP at 16. See also Pinheiro et al. *Factors Associated With Adherence To Antiretroviral Therapy In HIV/AIDS Patients: A Cross-Sectional Study In Southern-Brazil* 35(10) Braz J Med Biol Res. 1173 (2002); Landman et al., *Once-A-Day Highly Active Antiretroviral Therapy In Treatment-Naïve HIV-1-Infected Adults In Senegal* 17(7) AIDS 1017 (2003).

³⁶ Letter from Dr. Eric Goemaere to the Competition Commission (31 July 2003). The WHO explains: “this regime is of uncertain efficacy in patients with advanced disease” and that there is “only limited data on the use of ABC in pregnancy.” SCALING UP at 32.

³⁷ Fewer than 5 percent of people living with AIDS in developing countries who require immediate HAART to sustain their lives are receiving it; half of whom live in Brazil. WHO press release (9 July 2002), available at <http://www.who.int/inf/en/pr-2002-58.html>

Figure 1: HIV/AIDS Deaths and Treatment by Region, 2001



Source: UNAIDS (2002)

According to the WHO, limited access to ARVs is due to many factors:

Access to medicines depends on many factors, notably rational selection and use of drugs, adequate and sustainable financing, affordable prices, and reliable supply systems.³⁸

Among the prerequisites for accessing medicines, the WHO has emphasized that “[p]rices are only one factor.” In developing countries high prices are often determinative:

[P]rices are an important factor especially in developing countries, since, while in developed countries pharmaceuticals are largely publicly funded, through reimbursement and insurance schemes, in developing countries, typically, 50% to 95% of drugs are paid by the patients themselves. Thus in developing countries, prices of medicines have direct implications for access.³⁹

An affordability analysis has multiple dimensions. People may purchase needed medicines all or partly through household incomes, and therefore the amount of disposable income in households is relevant. In addition, people may receive medicines through private or public

³⁸ WHO Regional Office of the Western Pacific, 8 *HIV/AIDS Antiretroviral Newsletter* (December 2002).

³⁹ *Id.* See also WHO, *Information on Technical and Financial Cooperation Programmes carried out by the World Health Organisation and that are relevant to TRIPS Implementation and Access to Drugs* (2001) available at www.who.int/medicines/Organisation/ood/techcoop.shtml; WHO, *Globalization, TRIPS and access to pharmaceuticals*, WHO Policy Perspectives on Medicines No. 3, 5 (March 2001) (“Since most poor people in developing countries currently pay for health care, including drugs, out of their own pockets, access to medicines is particularly sensitive to cost.”); Ellen ‘t Hoen, *Trips, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 *Chicago Journal of International Law* 27, 28 (2002) (“Many factors contribute to the problem of limited access to essential medicines. Unavailability can be caused by logistical supply and shortage problems, substandard drug quality, inappropriate selection of drugs, wasteful prescription and inappropriate use, inadequate production, and prohibitive prices.”).

health insurance, and therefore national resources that are available for pooling are relevant. In each case, the evidence demonstrates that the respondents' best public and private sector prices are too high for South Africa to treat all those in need.

2.4.1 Household Affordability

There is a wide variation between the lowest offers by the respondents for their patented medications and the lowest offers by generic producers, some of whom have sought licences to introduce their products to South Africa.⁴⁰

- The least expensive three drug cocktail at private sector wholesale prices in South Africa (d4T+3TC+NVP) is priced at R14,435 per year; AZT+3TC+NVP is priced at R16,089.⁴¹
- The lowest priced generic version of dT+3TC+NVP costs R1,785 per year and generic AZT+3TC+NVP can be procured for R3,402 per year, vat inclusive.⁴²

At these prices, very few South Africans have sufficient earnings to enable purchase of the respondents' medicines through their household budgets. South Africa has a population of approximately 43.1 million people⁴³ and a GDP of \$104 billion (R780 billion)⁴⁴ yielding a GDP/person of R18,097. The distribution of income is highly unequal:

- The top 10% of the population by income collect 46.9% of the nation's income – R365.83 billion; R85,076 per person.⁴⁵
- The next 10% of income earners (4.3 million people) collected 20% of the national income – R152.86 billion; R35,466 per person.⁴⁶
- The bottom 80% of the population (34,48 million people) earned 33.5% of the national income – R261.3 billion; R7,578 per person.⁴⁷

The unequal distribution of income was reflected in the 1996 Census. The results showed that 43 percent of South African households earned less than R12,000 a year; 13 million (57 percent of population) was economically active, of whom 9.1 million were employed and 4.7 million were unemployed; 16 percent of South Africans had monthly income of R3,501 or more; 50 percent of African men and 69 percent of African women had monthly income of R1000 or less; 46.6 percent of African households earned less than R899 in monthly income and 26 percent of South Africans had incomes of R0-500 per month.⁴⁸ According to

⁴⁰ See discussion of the respondent's licensing practices below.

⁴¹ Mike Palmedo Expert Report, *Annex A – Antiretroviral Prices*. These figures are based on the Pharmaceutical Blue Book and include VAT and other expenses consumers must pay.

[REDACTED]

⁴² *Id.* table A-8, adjusted for South African VAT by dividing each quote by 0.86.

⁴³ SOUTH AFRICAN INSTITUTE OF RACE RELATIONS, SOUTH AFRICA SURVEY 2001/2002.

⁴⁴ World Bank, World Development Indicators Database 2002, www.worldbank.org/data/databytopic/GDP.pdf

⁴⁵ UNDP, 2003 *Human Development Report*.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ SOUTH AFRICA SURVEY (2001/2002).

government statistics, 61 percent of Africans, 38 percent of Coloureds, 5 percent of Indians and 1 percent of Whites “do not have at their disposable the means of achieving a minimum acceptable standard of living.”⁴⁹

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[REDACTED]

According to a recent WHO report:

A health care system is fairly financed if the ratio of total health system contribution of each household through all payment mechanisms to that household’s capacity to pay (effective non-subsistence income) is identical for all households, independent of the household’s health status or use of the health system.⁵¹

In South Africa, survey evidence suggests the average household in the top 20 percent income bracket spends three to five percent of their income on out of pocket medical expenses, including medicines.⁵² This level of expenditure is similar to that in the United States, including among poor families protected by the US Child Health Insurance Program.⁵³ Five percent of the income of an average earner in the top 20 percent income bracket would be approximately R3,009. The respondents’ prices for the cheapest first line treatment, which will not be appropriate for all people with AIDS,⁵⁴ are about five times this amount.

It should be noted that the use of five percent of household income above subsistence as a measure of a reasonable sustainable outlay for one medicine underestimates the lack of affordability for many. Household expenditure on health care includes all health care services for all members of households, including all medicines, physicians’ services, dental care and other needs. It is not uncommon for adults living together to be co-infected, doubling the costs of household costs for treatment, and even here, HAART is only one element of the medication and treatment that is required.

⁴⁹ *Id.* (citing NEDLAC statistics).

⁵⁰ [REDACTED]

⁵¹ Murray, Christopher and Felicia Knaul, Philip Musgrave, Ke Xu, and Kei Kawabata, *Defining and Measuring Fairness in Financial Contribution to the Health System*, World Health Organisation, GPE Discussion Paper No. 24 (emphasis added).

⁵² See Income and Expenditure Survey (IES) 2000, Statistics South Africa, available at www.statssa.gov.za; Integrated Household Survey 1993, World Bank, available at www.worldbank.org/html/prdph/lsmc/country/za94/za94data.html#top

⁵³ See Thomas J. Songer, Ronald E. LaPorte, Judith R. Lave, Janice S. Dorman and Dorothy J. Becker, *Health Insurance and the Financial Impact of IDDM in Families with an IDDM-affected Child* (undated study funded by National Institutes of Health concluding that median out of pocket expenditure on health care in the US, including insurance premiums, is 5 percent of household income.); 42 CFR § 457.560 (requiring participating states to cap poor family contributions to health at 5 percent of income).

⁵⁴ See the discussion on technical aspects of HAART, above, and Iris Boutros Expert Report.

2.4.2 Private Medical Scheme Affordability

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One supporting affidavit in this case indicates a disturbing development regarding how medical schemes are seeking to contain the costs of treating patients with AIDS. Mr. Leon Regensberg reports that some medical schemes are acting directly contrary to advice by the WHO by “still offering sub-standard mono- and dual therapy . . . because the high costs of drugs limit access to HAART within the available benefit structure.”⁵⁹ Lower prices may help public officials counter these cost saving measures which are harmful not only to patient health and welfare, but social welfare as well as it potentially contributes to viral drug resistance.

⁵⁵ See S. Thomas et al., *National Health Accounts Project: The Public Sector Report*. Pretoria: Department of Health (November 2000) (reporting that 18,6 percent of the South African population had some form of medical aid coverage in 1998).

⁵⁶ [REDACTED]

⁵⁷

[REDACTED]

⁵⁸ [REDACTED]

⁵⁹ Expert Affidavit of Mr. Leon Regensberg, Annexure LR to Tau Complaint; SCALING UP at 12 (noting that mono and dual ARV therapy is “no longer recommended as they do not adequately suppress HIV replication and are likely to lead to the rapid emergence of resistance”); *see also* id. at 29 (noting that “it is recognized that many HIV-infected individuals in the developing world are being treated with dual [nucleoside analogue reverse transcriptase inhibitor] combinations because potent three-drug and four-drug combinations are not affordable”).

Table 2: [REDACTED]⁶⁰

Source: Table by Mike Palmedo (2003)

No private insurance scheme has access to lower-priced generic versions of needed medicines. [REDACTED]

[REDACTED]

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[REDACTED]

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2.4.3 National Affordability

The respondents' public sector prices (R6,690 per year, vat inclusive, for AZT+3TC+NVP) are multiple times higher than the lowest-priced generic equivalent (R3,402 vat inclusive).⁶³

⁶⁰ [REDACTED]

⁶¹ [REDACTED]

⁶² [REDACTED]

⁶³ Mike Palmedo Expert Report, *Antiretroviral Prices*, Table A-9, converted to Rand by multiplying by 7.5 and adjusting for vat by dividing by .86.

By all reasonable measures, these prices are unaffordable for the purposes of treating all who need treatment from a reasonable proportion of the government's budget.

Treating the 1.2 million people who will need treatment by 2010 at the public sector price for AZT+3TC+NVP would demand approximately .9 percent of South Africa's current GDP for medicines alone.⁶⁴ That sum would be over half South Africa's spending on medicines (public and private sector combined) in 1998 and 1999 (1.7 and 1.4 percent of GDP respectively)⁶⁵ and would be a higher percentage of GDP than the world's established market economies spent on *all medicines* in 1990 (0.6 percent of GDP) (See Table 3 and Table 4).⁶⁶

Table 3: Pharmaceutical Expenditure by Region (1990)⁶⁷

Region	Pharmaceutical Expenditure		Pharmaceutical Expenditure By Source (%)	
	Total per Capita (\$USD)	As % of GDP	Public	Private
Established Market Economies	137.5	0.6	59.8	39.6 ⁶⁸
Middle East Crescent Economies in Transition	26.8	0.7	26.0	74.0
Latin America and Caribbean	19.5	-	-	-
Asia and Pacific	26.4	0.9	28.5	71.5
Sub-Saharan Africa	11.8	0.6	18.6	81.4
	7.8	0.9	33.2	66.8

⁶⁴ The actual costs of delivering medicines to people in need, including staff and related costs as well as the need for more expensive second line treatments, will be much higher. See *Summary Report of the Joint Health and Treasury Task Team Charged with Examining Treatment Options to Supplement Comprehensive Care for HIV/AIDS in the Public Sector* 14 (1 August 2003) (estimating that the cost of delivering a first year ARV regimen at respondents' prices will be R12,232 per year, and noting that "there is still considerable room for improvement from the current prices paid in South Africa to catch up with international best prices").

⁶⁵ Henry Dummett, *An Overview of Supply and Demand in South Africa's Pharmaceutical Industry—Opportunity or Risk* Pharmatech: Business Briefing, 49 (2002). South African spending on health care totals about 9 percent of GDP; medicines account for 18 percent of total healthcare expenditure. See WHO, 2002 World Health Report; UNDP, 2003 Human Development Report. The US spends the highest share of its GDP on health, 11.9 percent in 1990, and 13.9 percent in 2001. OECD countries as a whole have increased their share of GDP spent on health from 7.3 percent in 1990 to 8.4 percent in 2001. Organisation for Economic Co-operation and Development, data on health expenditures, available at: <http://www.oecd.org/dataoecd/10/20/2789777.pdf>

⁶⁶ Sarah Bennett et al., *Public-Private Roles in the Pharmaceutical Sector: Implications for Equitable Access and Rational Drug Use*, 32 World Health Organisation (1997). Spending on pharmaceuticals per capita increased by 90 percent (US) and 111 percent (Sweden) over the period 1990 to 2001, reaching 1.3 percent (Sweden) and over 1.5 percent (US) of GDP respectively. Organisation for Economic Co-operation and Development, data on medicines expenditures, available at: <http://www.ipha.ie/htm/info/download/Spending%20on%20Meds.%20as%20a%20share%20of%20spending%20on%20health%20care%20in%20the%20OECD.pdf>. Steven Schondelmeyer, an expert on the US pharmaceutical market, recently testified before the US Congress that spending on medicines in the US is now over 2 percent of GDP.

⁶⁷ Sarah Bennett et al., *Public-Private Roles in the Pharmaceutical Sector: Implications for Equitable Access and Rational Drug Use*, 32 World Health Organisation (1997).

⁶⁸ Established market economies data from Sarah Bennett et al., *Public-Private Roles in the Pharmaceutical Sector: Implications for Equitable Access and Rational Drug Use*, 32 World Health Organisation (1997), does not equal 100%.

Table 4: Pharmaceutical Expenditure in South Africa⁶⁹

	1995	1996	1997	1998	1999
Out-of-pocket					
Rand billion	5.9	6.6	7.3	8.0	8.9
\$US billion	1.6	1.4	1.5	1.4	1.5
Public Sector					
Rand billion	1.2	1.5	1.7	1.8	1.9
\$US billion	.333	.327	.347	.312	.311

There is no exact figure for the amount of GDP that should be spent specifically on ARVs. It is generally accepted that national affordability of medicines is a function of GDP and the number of people that need the medicine.⁷⁰ As Table 5 presents, South Africa has 0.2 percent of the income per person with AIDS as in the United States. Yet the public sector price being demanded by the respondents is about 10 percent of the US price.

Table 5: GDP per person Living with HIV/AIDS⁷¹

	Estimated Number of People Living with HIV/AIDS, end 2001 ⁷²	Total GDP, 2002 (thousands of US dollars) ⁷³	GDP per person Living with AIDS (US dollars)
Germany	41,000	\$1,976,240,000	\$48,200,976
United Kingdom	34,000	\$1,552,437,000	\$45,659,912
France	100,000	\$1,409,604,000	\$14,096,040
Italy	100,000	\$1,180,921,000	\$11,809,210
United States	900,000	\$10,416,818,000	\$11,574,242
Brazil ⁷⁴	610,000	\$452,387,000	\$741,618
Thailand	670,000	\$126,407,000	\$188,667
South Africa	5,000,000	\$104,235,000	\$20,847
Uganda	600,000	\$5,866,000	\$9,777
Kenya	2,500,000	\$12,140,000	\$4,856

The Joint Health and Treasury Task Team recommend that the government take proactive measures to decrease the cost of ARVs including:

- Strongly encouraging the granting of voluntary licences by patent holders for local manufacture⁷⁵

⁶⁹ Sarah Bennett et al., *Public-Private Roles in the Pharmaceutical Sector: Implications for Equitable Access and Rational Drug Use*, 32 World Health Organisation (1997).

⁷⁰ See James Love Expert Report, *Evaluation of Excessive Pricing of Certain Antiretroviral Drugs in South Africa*; see also F.M. Scherer Expert Report.

⁷¹ Calculations and table by Thiru Balasubramaniam.

⁷² UNAIDS/WHO Global Surveillance, Global Fact Sheets by country, 2002, www.unaids.org/hivaidsinfo/statistics/fact_sheets/index_en.htm

⁷³ World Bank, World Development Indicators Database, 2002 www.worldbank.org/data/datatopic/GDP.pdf

⁷⁴ Brazil is the only non-OECD country that has implemented a universal treatment programme.

- Using the provisions of Article 31 of TRIPS to move forward with compulsory licensing
- Initiating a fast-track process of negotiation with suppliers and “activation of legally permitted (but thus far unused) mechanisms to achieve access to high-quality ARV drugs at the best possible prices”

Assuming that these efforts will be targeted only at the government sector, e.g. utilizing legal authorisations for the government use of patented products without permission of the patent holder, they will not directly affect prices in the private sector. The current licence between GSK and Aspen Pharmacare is an example of an authorisation of generic supply for the government market only, which does not address affordability of medicines for people who purchase them through the private sector, including through medical aid schemes. Even if that license did cover the private sector, it alone would not enable the vibrant competition between suppliers needed to push prices to the lowest possible level.

The Joint Health and Treasury Task Team outlines 20 percent, 50 percent and 100 percent treatment options that a government programme of provision could adopt. Reflecting the constitutional obligation identified in *Grootboom*⁷⁶, the report states that “Any programme (including any ARV programme) must ensure that it meets the needs of those in ‘desperate need’ (i.e. the sickest and the poorest).”⁷⁷

The government’s proposals, unless the 100 percent public provision option is adopted, will leave substantial numbers of people in South Africa needing to purchase medicines out of their own income or through medical aid schemes. Indeed, the affordability of providing ARVs through the public sector is dependent on this fact. Yet at current private sector wholesale prices of R14,000 – R16,000 per year, only the very wealthiest portion of the population, or those who have access to the highest end medical schemes, can afford treatment with the respondents’ ARVs.

2.5 LICENSING PRACTICES OF THE RESPONDENTS

To analyse whether the respondents’ licensing practices are responsible for inhibiting access to low cost medicines, we analysed the information provided to the Commission

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[REDACTED]

⁷⁵ *Summary Report of the Joint Health and Treasury Task Team Charged with Examining Treatment Options to Supplement Comprehensive Care for HIV/AIDS in the Public Sector* 19 (1 August 2003). Note that the TRIPS agreement is not a national implementing statute.

⁷⁶ *Republic of South Africa v. Grootboom*, 2000 (11) BCLR 1169 para 44.

⁷⁷ *Id.* at 18.

⁷⁸ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

2.5.1 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁸⁰

[REDACTED]

⁷⁹ [REDACTED]
⁸⁰ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁸¹

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁸³ There are two regional patent systems in Africa, the Organisation Africaine de la Propriete Intellectuelle (OAPI) and the African Regional Industrial Property Organisation (ARIPO), through which a patent holder can file in a central office and obtain patent recognition in multiple countries. Whether an individual patent is recognised depends on the date of promulgation of each country's patent law. See Carlos Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, World Health Organisation, Health Economics and Drugs EDM Series No. 12, 38-40 (2002).

⁸⁴ [REDACTED]

⁸⁵ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

24 April 2001: GSK admits to not having valid patents in Ghana and Uganda

On 24 April 2001, Glaxo Wellcome apologised for its actions in Ghana and Uganda, admitting that it had no enforceable patents in those countries and stating that the threats were “mistakes of an overzealous company official.”⁸⁷

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[REDACTED]

[REDACTED]

[REDACTED]

⁸⁶ [REDACTED]

⁸⁷ The Times of India, *Violation Charges against Cipla a mistake: Glaxo* (24 April 2001).

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[REDACTED]

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⁹¹ [REDACTED]

⁹² [REDACTED]

⁹³ [REDACTED]

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2.5.2 GlaxoSmithKline Licence to Aspen Pharmacare

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2.5.3 [REDACTED]

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⁹⁵ [REDACTED]

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⁹⁸ [REDACTED]

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¹⁰³ [REDACTED]

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¹⁰⁵ [REDACTED]

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2.5.4 [REDACTED]

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[REDACTED]

¹⁰⁶ [REDACTED]

¹⁰⁷ According to Boehringer Ingelheim's 2002 Licensing Brochure they have entered into licensing agreements with Pharmacia (Tipranavir, 2000), Yamanouchi (FLOMAX, 1993), Genentech (Actilyse/Metalyse, 1983), Neurosearch (NS-2330, 2001), Kissei (2002), ImmunoGen (2001, development and licensing agreement) and collaboration agreements with Eli Lilly & Company (Duloxetine, 2002) and Sagres Discovery (2002). Boehringer Ingelheim, Licensing Brochure, 2002 www.boehringer-Ingelheim.com/corporate/home/Licensing2002.pdf

¹⁰⁸ [REDACTED]

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SECTION 3: SOUTH AFRICAN AND COMPARATIVE LAW

3.1 NORMATIVE PRINCIPLES OF INTERPRETATION

Section 1(2) of the Competition Act instructs that the Act must be interpreted –

- (a) in a manner that is consistent with the Constitution and gives effect to the purposes set out in section 2; and
- (b) in compliance with the international law obligations of the Republic.

The Constitution, South Africa’s international law obligations and the purposes of the Competition are in accord. Read together, they require that South Africa’s competition authorities adopt interpretations of the Competition Act that increase access to medicines needed to address public health concerns.

3.1.1 South African Constitution

The South African Constitution sets as its primary objectives the promotion of “human dignity, the achievement of equality and the advancement of human rights and freedoms.”¹¹⁹ To meet these goals, it establishes a Bill of Rights that “applies to all law, and binds . . . all organs of state”, including the Competition Commission and the Competition Tribunal.¹²⁰

The Constitution’s Bill of Rights includes so called ‘second generation’ rights that create enforceable duties on the state to “respect, protect, promote and fulfil” a series of social and economic rights. South Africa’s Constitutional Court has described these rights as emanating from, and requiring that the state abide by, the principle that “[a] society must seek to ensure that the basic necessities of life are provided to all if it is to be a society based on human dignity, freedom and equality.”¹²¹

At the centre of the social and economic rights provisions in the Constitution is the parallel treatment of the rights to health care, food, water and social security. These rights are all provided in the same section (section 27), suggesting that they should be considered as complementary and of similar significance.

In relation to health care, the Constitution states:

- (1) Everyone has the right to have access to –
 - (a) health care services, including reproductive health care;
 -
- (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
- (3) No one may be refused emergency medical treatment.

¹¹⁹ Preamble to the Constitution of South Africa.

¹²⁰ Sec. 8.

¹²¹ *Republic of South Africa v. Grootboom*, 2000 (11) BCLR 1169 para 44

Section 28 further defines the rights of children as including the right “to basic nutrition, shelter, basic health care services and social services.”

Section 39(1) requires that “[w]hen interpreting any legislation,” such as the Competition Act, “every court, tribunal or forum must promote the spirit, purport and objects of the Bill of Rights.” Section 39(2) requires that the Bill of Rights, and the obligations of the state to fulfil them, must be interpreted with consideration of international law, such as international human rights obligations described in 3.1.2.

In the recent case of *Minister of Health v Treatment Action Campaign*¹²², the Constitutional Court held that the government’s restrictions on the use of NVP for prevention of mother-to-child transmission of HIV violated Section 27. In so doing, the Court implicitly affirmed that access to needed medicines is a component of the right to health services that the state must progressively realise and promote through its interpretation of any legislation.

One component of the state’s duty to fulfil social and economic rights is to create and implement programmes that address the basic needs of those that cannot provide for themselves.¹²³ This obligation is reflected in the Report of the Joint Health and Treasury Task Team Charged with Examining Treatment Options to Supplement Comprehensive Care in the Public Sector.¹²⁴

The state’s duties under Section 27 do not end with programmes targeted to the needs of the most desperate. As the Constitutional Court explained with respect to the duty to promote access to housing, “other agents within our society, including the individuals themselves, must be enabled by legislative and other measures”; “The state must create the conditions for access . . . for people at all economic levels of our society”, including by “unlocking the system” where market barriers inhibit the enjoyment of rights.¹²⁵

The application of the Competition Act to the use of intellectual property rights by dominant firms to inhibit consumer access to affordable medicines is precisely the kind of situation where interpretations of law that promote the spirit and purport of the right to health are needed to unlock the system for those who cannot now access needed medicines.

3.1.2 Human Rights Obligations¹²⁶

South Africa has international law obligations that arise from international human rights conventions. These obligations parallel, and give context to, the obligations included in the South African Constitution. Here, we briefly discuss two central human rights that must inform the interpretation of the Competition Act: the right to health and the right to benefit from scientific progress.

¹²² 2002 (5) SA 721 (cc); 2002 (10) BCLR 1033 (cc)

¹²³ See *Republic of South Africa v. Grootboom*, 2000 (11) BCLR 1169, paras 41-44.

¹²⁴ See *Summary Report* at 18 (“Any programme (including any ARV programme) must ensure that it meets the needs of those in ‘desperate need’ (i.e. the sickest and the poorest.)”); see also *Appendix 4: Legal and Constitutional Considerations*.

¹²⁵ *Grootboom*, paras 35-35; see also *Minister of Health v. Treatment Action Campaign*, para 70 (“There is a difference in the positions between those who can afford to pay for [health] services and those who cannot. State policy must take account of these differences.”).

¹²⁶ For an expanded analysis, see Alicia Yamin Expert Report

3.1.2.1 Sources of the Right to Health

A large number of international human rights agreements include obligations related to recognition of a right of everyone to have access to health care.. These specific obligations may be seen as flowing from the more general human rights obligation of every state to protect life – one of the most basic and important of all human rights guarantees.¹²⁷

Article 12 in Section 1 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR) contains the fullest articulation of “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”¹²⁸ Section 2 states:

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

- (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases, and
- (d) The creation of conditions which would ensure to all, medical service and medical attention in the event of sickness.¹²⁹

A host of other binding agreements and United Nations declarations contain supporting recognitions of a right to health, and corresponding duties of states to take measures to promote access to health care:

- The International Convention on the Elimination of All Forms of Racial Discrimination of 1965 calls on States Parties to eliminate racial discrimination and “guarantee the right of everyone, without distinction of race, colour, or national or ethnic origin” to the enjoyment of, among other rights, “the right to public health, medical care, social security and social services.”¹³⁰
- Article 12 of the Convention on the Elimination of All Forms of Discrimination Against Women of 1979 affirms: “States Parties shall take all appropriate measures to eliminate discrimination against women in the field of

¹²⁷ See Yamin Expert Report, explaining:

Given that medications can be indispensable for life, it is foreseeable that State policies that are likely to lead directly to diminished physical accessibility and affordability of certain medications in effect will deprive people of life. . . . The right to life has generally been recognized to encompass more than not dying as a result of actions directly attributable the State, to extend to conditions that permit at a minimum survival if not those that are conducive to dignity and well-being. . . . Specifically, the Human Rights Committee has defined the role of the state in protecting human life to include obligations to reduce infant mortality, increase life expectancy, eliminate malnutrition and epidemics.

¹²⁸ International Covenant on Economic, Social and Cultural Rights, adopted 16 Dec. 1966, G.A. Res 2200 (XXI), U.N. GAOR 21st Sess. Supp. No. 16, at 49, U.N. Doc A/6316 (1966), 993 U.N.T.S. 3 (entered into force 3 Jan 1976) at Art. 12(1). [ICESCR]

¹²⁹ Id, at Art. 12(2)(c)and(d), respectively.

¹³⁰ International Convention on the Elimination of all Forms of Racial Discrimination, adopted by UNGA 21 Dec. 1965, UN GAOR Res. 2106 A(XX) (entered into force 4 Jan 1969), reprinted in *Twenty-Five Human Rights Documents*. (NY; Columbia University:1994).

health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.”¹³¹

- Article 24(1) of the Convention on the Rights of the Child states: “States Parties recognise the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.”¹³²
- The Universal Declaration of Human Rights states in Article 25(1): “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.”¹³³

3.1.2.2 Obligations of the Right to Health

In its General Comment No. 14 on the “Right to the Highest Attainable Standard of Health,” the United Nations Economic, Social and Cultural Rights Committee (ESCR Committee) explained that all human rights impose “three types or levels of obligations on States parties: the obligations to respect, protect and fulfil.”¹³⁴

The obligation to fulfil requires States “to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health.”¹³⁵ This includes an obligation “to take all necessary steps to ensure the realization of the right to health,” including “measures to reduce the inequitable distribution of health facilities, goods and services” and measures to ensure that health facilities, goods and services are “affordable for all”.¹³⁶

The obligation to “protect” the right to health includes the duty “to regulate the activities of individuals, groups or corporations,” such as the multinational companies that control access to anti-AIDS drugs, “so as to prevent them from violating the right to health of others.”¹³⁷

It is clear that fulfilment of the right to health requires access to needed medicines.¹³⁸ General Comment No. 14 states a minimum requirement that every state take every possible

¹³¹ Convention on the Elimination of all Forms of Discrimination against Women, adopted 18 Dec. 1979, G.A. Res. 34/180, U.N. GAOR 34th Sess., Supp/ No. 44 at 193, U.N. Doc. A/34/36 91980)(entered into force 3 Sept. 1981).

¹³² Convention on the Rights of the Child (adopted 20 Nov. 1989) G.A. Res 44/25 U.N. GAOR, 44th Sess., Supp. No. 49 at 167, U.N. Doc. A/44/49 (1989) (entered into force 2 Sept. 1990).

¹³³ Universal Declaration on Human Rights, adopted 10 Dec. 1948, UNGA Res. 217 A (III) reprinted in *Twenty-Five Human Rights Documents*. (NY; Columbia University:1994) at art. 25. Professor Yamin’s report notes that “Although not a treaty, the Universal Declaration is generally considered to be an authoritative interpretation of human rights obligations of member States under Articles 55 and 56 of the United Nations Charter.”

¹³⁴ General Comment No. 14, UN Committee on Economic, Social and Cultural Rights.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ ESCR Committee General Comment No. 14 at para 51.

measure to provide “the underlying determinants of health, such as . . . essential drugs, as defined by the WHO Action Programme on Essential Drugs.”¹³⁹ According to the Comment, the provision of essential drugs identified on the WHO’s Model List of Essential Medicines is part of each state’s “core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in the Covenant, including essential primary health care.”¹⁴⁰

In 2001, the UN Commission on Human Rights specifically addressed the human rights implications of access to medicines for the treatment of HIV/AIDS.¹⁴¹ The Commission recognised “that access to medication in the context of pandemics such as HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”. The Commission, therefore described a human rights duty “to pursue policies, in accordance with . . . international agreements acceded to, which would promote . . . [t]he availability in sufficient quantities of pharmaceuticals and medical technologies” used to treat HIV/AIDS and the most common opportunistic infections that accompany them.¹⁴²

3.1.2.3 The Right to Benefit from Scientific Progress

In addition to the right to health, there is a specific internationally recognised human right to benefit from scientific progress, which creates a duty to adopt policies and programmes, including interpretation of national laws and international trade agreements, toward this goal.

Article 15 of the ICESCR states that States Parties “recognize the right of everyone . . . [t]o enjoy the benefits of scientific progress and its applications”. In 2001, the ESCR Committee adopted a General Statement on Human Rights and Intellectual Property “to identify some of the key human rights principles that are required to be taken into account in the development, interpretation and implementation of contemporary intellectual property regimes.”¹⁴³ The General Statement underscores that “the realms of trade, finance and investment are in no way exempt from human rights principles” and that both national legislation and international rules and policies relating to intellectual property protection must abide by international human rights law.¹⁴⁴

The General Statement of the ESCR commented that intellectual property protection cannot, consistent with human rights duties, be treated as an end in itself. Rather, “the end which intellectual property protection should serve is the objective of human well-being, to which international human rights instruments give legal expression.”¹⁴⁵ It, therefore, clarified that

¹³⁸ See Professor Yamin’s expert report, which describes the “growing jurisprudence at both national and international levels that supports the notion that the provision of access to life-saving medications constitutes an integral part of the right to life, as well as the right to health.”

¹³⁹ ESCR Committee General Comment No. 14 at para 12.

¹⁴⁰ *Id.* at para 43.

¹⁴¹ Resolution 2001/33.

¹⁴² This statement reaffirmed the principles agreed to by UN member states in the United Nations Declaration of Commitment on HIV/AIDS, UN General Assembly 26th Special Sess. Res. 33/2001. 25-27 June 2001.

¹⁴³ “Human Rights and Intellectual Property” Statement by the Committee on Economic, Social and Cultural Rights,” Follow-up to the day of general discussion on article 15.1(c), 26 November 2001, E/C.12/2001/15, 14 Dec. 2001, para 2.

¹⁴⁴ *Id.* at para 3.

¹⁴⁵ *Id.* at para 4.

“any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, food, education, especially, or with any other right set out in the Covenant is inconsistent with the legally binding [human rights] obligations of the state party.”¹⁴⁶

3.1.3 The Trips Agreement¹⁴⁷

South Africa is a member state of the World Trade Organisation (WTO) and a party to the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). The TRIPS agreement establishes minimum safeguards for the protection of intellectual property rights in each member state. Competition policy as it affects products covered by intellectual property protection is an area explicitly covered by TRIPS requirements. The agreement therefore defines important international law obligations against which the Competition Act must be interpreted.¹⁴⁸

Towards the goal of ensuring that states are able to protect public health and other public interests, TRIPS contains numerous safeguards and flexibilities permitting limitations to patent rights, including through compulsory licensing.¹⁴⁹ Countries maintain complete flexibility under TRIPS to determine the grounds for issuance of a compulsory licence. This right was reiterated by the Doha Declaration on the TRIPS Agreement and Public Health, issued at the 2001 WTO Ministerial Meeting held in Doha, Qatar, which stated: “Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”¹⁵⁰.

It has often been reported that TRIPS makes compulsory licensing available only in cases of emergency, but this is incorrect. TRIPS states only that, in situations of emergency, countries are permitted to bypass the obligation to undertake negotiations for a voluntary licence in advance of issuing a compulsory licence.¹⁵¹

3.1.3.1 Enhanced Flexibility to Remedy Anti-Competitive Practices

While TRIPS does not impose limitations on the grounds for compulsory licensing, it does mandate that certain procedures be followed in consideration of compulsory licence requests.¹⁵² The TRIPS rules provide for special treatment of compulsory licences issued to

¹⁴⁶ *Id* at para 12.

¹⁴⁷ For an expanded analysis, see Robert Weissman Expert Report (B), *The World Trade Organisation’s Agreement on Trade-Related Aspects of Intellectual Property*.

¹⁴⁸ In joining the WTO, members accede to 18 agreements annexed to the agreement establishing the WTO. For a brief history of the rounds of GATT negotiations from 1947 to the creation of the WTO in 1994, see Boulet, *Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement*, WHO Action Programme on Essential Drugs, DAP Series No. 7, 9-15 (1999 revised) available at www.who.int/medicines/library/dap/who-dap-98-9-rev/who-dap-98-9.htm (describing Paris Convention of 1883); see also UNDP, Human Development Report 2001 at 106 (noting that prior to TRIPS, 50 countries did not provide patent protection for pharmaceutical products, and 40 countries did not patent pharmaceutical processes or products).

¹⁴⁹ Compulsory licensing is the authorisation by a government for a third party to make use of a patent, without the consent of the patent holder.

¹⁵⁰ Doha Declaration on the TRIPS Agreement and Public Health, Paragraph 5.

¹⁵¹ TRIPS Article 31(b).

¹⁵² For all compulsory licences, TRIPS requires that:

remedy anti-competitive practices. In such cases, countries maintain the flexibilities available for compulsory licensing generally, including that they may define anti-competitive practices for which compulsory licensing is a presumptive or possible remedy as they see fit.

There are three enhanced flexibilities for compulsory licensing to remedy anti-competitive practices:

First, a prior effort to negotiate voluntary licences is not necessary.¹⁵³

Second, countries do not need to require that compulsory licences issued to remedy anti-competitive practices be used predominantly for the domestic market.¹⁵⁴ This is important to give competitors the economies of scale necessary to make efficient use of a compulsory licence and enter into meaningful competition with the patent holder.¹⁵⁵ Authorisation for export through anticompetition findings may also enable the supply of less developed countries that lack manufacturing capacity.¹⁵⁶

Third, “the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases.”¹⁵⁷ This includes the option of zero-royalty licensing.

3.1.3.2 The Implications of the Doha Declaration

African countries proposed that the 2001 Ministerial Conference on the TRIPS agreement clarify the available mechanisms that developing countries can use to promote access to affordable medicines.¹⁵⁸ The Ministerial Conference has “the exclusive authority to adopt

-
- Compulsory licensing requests be considered on their individual merits (Article 31(a))
 - The right holder must be paid adequate remuneration, considering the need to remedy anticompetitive practices (31(h));
 - Both the decision to issue a compulsory licence and the level of remuneration must be subject to judicial or administrative review (31(i) & (j)).

For compulsory licences outside of the competition law context, Trips requires:

- Consideration of compulsory licences be preceded by efforts to negotiate voluntary licences on reasonable commercial terms, and that such efforts have not been successful within a reasonable period of time (31(b));
- Authorised use must be predominantly for the domestic market (31(f)).

¹⁵³ TRIPS Article 31(k)

¹⁵⁴ *Id.*

¹⁵⁵ See Robert Weissman Expert Report, *Economies of Scale are Important and a Compulsory License Must Permit Exports so that a Domestic Producer Can Reach Efficient Economies of Scale* (Expert Report RW(C))

¹⁵⁶ Although small market countries are able to issue compulsory licences, including for importation, they may not be able to find any TRIPS-legal exporters, since the exporters are restrained by patents in their home countries. Even if compulsory licences are issued in the exporting country, licensees must normally produce predominantly for the domestic market, according to Article 31(f). If countries issue compulsory licences pursuant to Article 31(k) to remedy anti-competitive practices, the licensees are not subjected to the Article 31(f) limitation.

¹⁵⁷ TRIPS Article 31(k)

¹⁵⁸ See Ellen ‘t Hoen, *Trips, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 *Chicago Journal of International Law* 27, 30-42 (2002); Carlos Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, World Health Organisation, Health Economics and Drugs, EDM Series No. 12, 1 (2002) (describing the African Group’s request as growing from concerns about “[t]he HIV crisis in sub-Saharan African countries, the attempts by the pharmaceutical industry, backed

interpretations” of the TRIPS agreement,¹⁵⁹ and therefore the Doha Declaration has legal effects on Member States and WTO bodies.¹⁶⁰

The declaration issued by the Ministerial Conference on TRIPS and Public Health recognised “the gravity of public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”¹⁶¹ It asserts that TRIPS must serve as “part of the wider national and international action to address these problems.”¹⁶² The declaration also recognised, and sought to address, “concerns about effects [of patents] on prices” of medicines.¹⁶³

Paragraph four of the Doha Declaration records the agreement of all member states that:

[T]he 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.

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.¹⁶⁴

Paragraph five of the Declaration reaffirms that states possess “the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”.¹⁶⁵ It also explains that states have “the right to determine what constitutes a national emergency or other circumstances of extreme urgency” that may justify streamlined procedures for a compulsory licence, “it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency”.¹⁶⁶

Paragraphs six and seven of the Declaration contain provisions specifically targeted to pharmaceuticals.¹⁶⁷ Professor Carlos Correa explains:

by some governments, to block the implementation of TRIPS-complaint measures by the South African government, and the complaint brought by the USA against Brazil in relation to compulsory licenses”).

¹⁵⁹ Article IX(2), *Decision-Making*, in RAJ BHALA, *INTERNATIONAL TRADE LAW: CASES AND MATERIALS* 86 (1996) (Documents Supplement)

¹⁶⁰ Carlos Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, World Health Organisation, EDM Series No. 12, WHO/EDM/PAR/2002.3 43-44 (2002).

¹⁶¹ Paragraph one of the Doha Declaration.

¹⁶² Doha Declaration on the TRIPS Agreement and Public Health, Paragraph Two.

¹⁶³ Paragraph three of the Doha Declaration.

¹⁶⁴ Paragraph four of the Doha Declaration.

¹⁶⁵ Paragraph 5(b) of the Doha Declaration.

¹⁶⁶ Paragraph 5(c) of the Doha Declaration.

¹⁶⁷ Paragraph Six of the Doha Declaration obligated WTO members to craft a pharmaceutical-specific solution to the compulsory licensing problems faced by countries with markets too small to achieve economies of scale:

We recognise 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.”).

Similarly, paragraph Seven of the Doha Declaration specifically authorises differential treatment of pharmaceuticals, permitting Least-Developed Countries not to enforce patents on pharmaceuticals until 2016:

It is implicit within the Doha Declaration that differentiation in patent rules may be necessary to protect public health. The singling out of public health, and in particular pharmaceuticals (paragraphs 6 and 7), as an issue needing special attention in TRIPS implementation constitutes recognition that public health-related patents deserve to be treated differently from other patents.¹⁶⁸

3.1.4 Purposes of the Competition Act¹⁶⁹

A final source of interpretive guidance required to be consulted by the Competition Act is the purposes that the Act was designed to further. Section 2 of the Act states: “The purpose of this Act is to promote and maintain competition in the Republic”. Protection of the competitive process is a means to the ultimate end of increasing consumer and national welfare.¹⁷⁰ Thus, the Preamble to the Act states that “[a]n efficient, competitive economic environment, balancing the interests of workers, owners and consumers and focussed on development, will benefit all South Africans.”¹⁷¹ Similarly, Section 2 of the Act defines the purposes to be promoted through interpretation to include:

- (a) to promote the efficiency, adaptability and development of the economy;
- (b) to provide consumers with competitive prices and product choices;
- (c) to promote employment and advance the social and economic welfare of South Africans;
- (d) to expand opportunities for South African participation in world markets and recognise the role of foreign competition in the Republic;

The paramount interests of consumers are reflected in legislative history of the Act. The Department of Trade and Industry's Proposed Guidelines for Competition Policy include that competition policy counter the “efficiency and distributional consequences of significant concentrations of economic power” that lead to “pricing behaviour prejudicial to consumers.”¹⁷²

The legislative history of the Act further clarifies that equity and development considerations are not to be treated as platitudes, but equal and complementary policy goals alongside

We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016 ...

¹⁶⁸ Carlos Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, World Health Organisation, June 2002, 40.

¹⁶⁹ For expanded analysis, see Robert Weissman Expert Report (A), *The Purposes of the South African Competition Act*.

¹⁷⁰ See *Northern Pacific Railway v. United States*, 356 US 1 (1958) (“The Sherman Act was designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade. It rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress, while at the same time providing an environment conducive to the preservation of our democratic political and social institutions.”).

¹⁷¹ Competition Act, Preamble.

¹⁷² *Proposed Guidelines for Competition Policy: A Framework for Competition, Competitiveness and Development*, Department of Trade and Industry 8.1.1 (27 November 1997).

efficiency objectives.¹⁷³ Thus, the Department of Trade and Industry's Guidelines asserted that competition policy accepts the logic of market competition and importance of property rights “within a developmental context that consciously attempts to correct structural imbalances and past economic injustices.”¹⁷⁴ “It is therefore critical,” the Guidelines continued, “that all government policies -- including competition policy -- are aligned so as to reduce the uneven development, inequality and absolute poverty which is so prevalent in South Africa.”¹⁷⁵

It is finally notable that the Act was intended to be mindful of South Africa's impact on economically weaker countries in the region.¹⁷⁶ This fact is relevant to the consideration of remedies in this case. As described elsewhere, a compulsory licence order may aid economically weaker countries by (1) providing a source for imports and (2) push prices lower by promoting economies of scale.¹⁷⁷

3.2 COMPARATIVE LAW

The Competition Act instructs that, in addition to the normative principles discussed above, “Any person interpreting or applying this Act may consider appropriate foreign and international law.”¹⁷⁸ Comparative law from the United States, the European Community and Canada demonstrate that there is a wide range of acceptable approaches for applying competition regulations to intellectual property owners. These approaches range from standards that grant Intellectual Property owners immunity from obligations to licence others (in a limited number of US cases) to approaches that create heavy presumptions in favour of licensing all pharmaceutical patents (Canada from 1923-1992).

3.2.1 United States

The Sherman Act of 1890 prohibits acts or attempts to “monopolize” any part of trade or commerce.¹⁷⁹ There is no exemption in the Act for owners of intellectual property rights.¹⁸⁰

¹⁷³ As New York University Professor Eleanor Fox has pointed out, South Africa's decision to simultaneously pursue efficiency, equality and distributional considerations in its competition policy may not only be a legitimate choice for the nation, but the most effective means to achieve efficiency goals: “Until the disempowered fully participate in the economy, the efficiency potential of the nation is not likely to be realized.” Eleanor Fox, *Equality, Discrimination, and Competition Law: Lessons From and For South Africa and Indonesia*, Harvard International Law Journal, 41 Harv. Int'l L.J. 579, 593 (2002).

¹⁷⁴ *Proposed Guidelines for Competition Policy: A Framework for Competition, Competitiveness and Development*, Department of Trade and Industry 2.4.11 (27 November 1997).

¹⁷⁵ *Proposed Guidelines for Competition Policy: A Framework for Competition, Competitiveness and Development*, Department of Trade and Industry 10.1 (27 November 1997).

¹⁷⁶ *Proposed Guidelines for Competition Policy: A Framework for Competition, Competitiveness and Development*, Department of Trade and Industry 2.4.2 (27 November 1997).

¹⁷⁷ See Robert Weissman Expert Report, *Economies of Scale are Important and a Compulsory License Must Permit Exports so that a Domestic Producer Can Reach Efficient Economies of Scale* (Expert Report RW(C)).

¹⁷⁸ Section 1(3).

¹⁷⁹ 15 USC. § 2 states:

Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony

¹⁸⁰ As one of the first Acts of the first Congress in 1790, the US Patent Act predates the Sherman Act by a century. See *Sears v. Stiffel*, 376 US 225, 228-29 (1964) (tracing the first patent laws in the US to state legislation enacted before the Constitution was adopted, and noting that the first federal patent law was passed

In *United States v. Grinnell*, 384 US 563, 570-71 (1966), the Supreme Court described the Sherman Act monopolisation offence as being composed of two elements:

- (1) the possession of monopoly power in the relevant market, and
- (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.¹⁸¹

Where a patent confers market power, it is settled law in the US that certain licensing practices may violate the Sherman Act despite the fact that the patent confers “the right to exclude others from the use of the invention, absolutely or on the terms of the patentee.”¹⁸² The Supreme Court has firmly and repeatedly held that “patents afford no immunity from the anti-trust laws.”¹⁸³

The question of when, if ever, a patent holder may violate the Sherman Act by a unilateral refusal to licence its intellectual property to a competitor is uncertain. This section describes the basic doctrines covering refusals of a monopolist to deal with others outside of the intellectual property context, and then notes the division in US Courts regarding how those doctrines should be applied to cases involving intellectual property rights.

in 1790); *cf.* US Const. art. I, s 8, cl. 8 (empowering Congress “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”). Some courts and commentators have explained the lack of an exemption as flowing in part from recognition that “intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare.” US Department of Justice and Federal Trade Commission *Antitrust Guidelines for the Licensing of Intellectual Property* (Section 1.0) (explaining that “intellectual property laws provide incentives for innovation and its dissemination and commercialization by establishing property rights for the creators of new and useful products, more efficient processes, and original works of expression. . . . The antitrust laws promote innovation and consumer welfare by prohibiting certain actions that may harm competition with respect to either existing or new ways of serving consumers.”); *see also* JULIAN O VON KALINOWSKI, ET AL, *ANTITRUST LAWS AND TRADE REGULATION*, 2D ED. VOL 2, 7A-5 n.5 (2003) (“there is no inherent conflict between the rights granted under a patent and the principles underlying the antitrust laws, any more than there is an inherent conflict between any notion of private property and the antitrust laws”); *cf.* *Times-Picayune Publishing Co. v. United States*, 345 US 594, 605 (1953) (“Basic to the faith that a free economy best promotes the public wealth is that goods must stand the cold test of competition”; antitrust laws help ensure that “the public, acting through the market’s impersonal judgment, shall allocate the Nation’s resources and thus direct the course its economic development will take.”).

¹⁸¹ The Supreme Court applies a purposive approach to interpreting the Act, evaluating claims from “from the standpoint of the consumer – whose interests the statute was especially intended to serve”. *Jefferson Parish Hosp v Hyde*, 466 US 2, 15 (1984).

¹⁸² *United States v. United Shoe Mach. Co.*, 247 US 32, 57 (1918).

¹⁸³ *International Salt v. United States*, 332 US 392, 395-96 (1947); *accord Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 US 502 (1917); *see also Kodak v. Image Technical Services*, 504 US 451, 479 n.29 (1992) (“The Court has held many times that power gained through some natural and legal advantage such as a patent, copyright, or business acumen can give rise to liability if ‘a seller exploits his dominant position in one market to expand his empire into the next.’”); *cf. Square D Co. v. Niagara Frontier Tariff Bureau, Inc.*, 476 US 409, 421 (1986) (“exemptions from the antitrust laws are strictly construed and strongly disfavored.”).

3.2.1.1 The Possession of Monopoly Power

As noted by the Court in *United States v. Grinnell*, the first step in any Sherman Act analysis is to determine whether the defendant has “monopoly power”. Market power in US antitrust analysis refers to “the power to control prices or to exclude competition.”¹⁸⁴

The first step to determining whether a defendant has monopoly power is to define the relevant market. Product markets in US law are defined on the basis of “reasonable interchangeability”.¹⁸⁵ A product market is one for which there are no effective substitutes, where “[a]n ‘effective substitute’ is one close enough to the examined good that it becomes a substitute when the price of the examined good rises” 5-10 percent above the competitive level.¹⁸⁶ This test is reflected in the US Horizontal Merger Guidelines, which define a relevant market as the narrowest product market in which a hypothetical monopolist is able to profitably impose a “small but significant and nontransitory” increase in price, i.e. without a large enough reduction in sales from substitution that the price increase would be unprofitable.¹⁸⁷ Using the test, US courts narrowly define the relevant market for antitrust analysis, often limiting the market to a single branded product.¹⁸⁸

¹⁸⁴ *United States v. E.I. du Pont de Nemours & Co.*, 351 US 377, 391 (1956).

¹⁸⁵ *Brown Shoe v. United States* 370 US 294, 325 (1962) (“The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it”; similarly, the boundaries of a relevant submarket “may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product’s peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialised vendors.”).

¹⁸⁶ HERBERT HOVENKAMP, MARK JANIS AND MARK LEMLEY, *IP AND ANTITRUST* 4-41 (2002); *see also SmithKline Corp. v. Ely Lilly & Co.*, 575 F.2d 1056, 1063 (3d Cir. 1978) (stating that the relevant antitrust market should include only those products that “have the ability -- actual or potential -- to take significant amounts of business away from each other.”); *H.J. Inc. v. International Tel. & Tel. Corp.*, 867 F.2d 1531, 1537 (8th Cir. 1989) (A relevant product market is one where “sellers, if unified by a hypothetical cartel or merger, could raise prices significantly above the competitive level”); *accord United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 (8th Cir. 1988).

¹⁸⁷ Under the Merger Guidelines,

A market is defined as a product or group of products and a geographic area in which it is produced or sold such that a hypothetical profit-maximising firm, not subject to price regulation, that was the only present and future producer or seller of those products in that area likely would impose at least a “small but significant and nontransitory” increase in price, assuming the terms of sale of all other products are held constant.

....

Specifically, the Agency will begin with each product (narrowly defined) produced or sold by each merging firm and ask what would happen if a hypothetical monopolist of that product imposed at least a “small but significant and nontransitory” increase in price, but the terms of sale of all other products remained constant. If, in response to the price increase, the reduction in sales of the product would be large enough that a hypothetical monopolist would not find it profitable to impose such an increase in price, then the Agency will add to the product group the product that is the next-best substitute for the merging firm's product.

....

The price increase question is then asked for a hypothetical monopolist controlling the expanded product group. . . . The Agency generally will consider the relevant product market to be the smallest group of products that satisfies this test.

Department of Justice and Federal Trade Commission 1992 Horizontal Merger Guidelines, Sections 1.0 and 1.11.

The Guidelines explain that “to determine objectively the effect of a ‘small but significant and nontransitory’ increase in price, the Agency, in most contexts, will use a price increase of five percent lasting for the foreseeable future. However, what constitutes a ‘small but significant and nontransitory’ increase in price will

The issue of market or monopoly power is closely related to market definition.¹⁸⁹ If a firm has the ability to profitably raise prices for a product more than 5-10 percent above the competitive price (i.e. without large enough decrease in sales from substitution so as to make the increase unprofitable), then it has monopoly power.¹⁹⁰

Whether a patent holder has market power is determined by application of the same test, which normally turns on whether there are sufficient substitutes in the relevant market to control pricing behaviour. Thus, although the Supreme Court has sometimes referred to patent law as protecting a “monopoly”,¹⁹¹ and has presumed that patents confer market power,¹⁹² it has explained that “a patent holder has no market power in any relevant sense if there are close substitutes for the patented product.”¹⁹³

depend on the nature of the industry, and the Agency at times may use a price increase that is larger or smaller than five percent.” *Id.* at 1.11.

¹⁸⁸ See *Times-Picayune Publishing Co. v. United States*, 345 US 594, 612 n.31 (1953) (explaining that the relevant product market “must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn”); *Community Publishers v. Donrey Corp.*, 892 F.Supp. 1146, 1161 (W.D. Ark. 1995) (“the approaches to market definition endorsed by the Merger Guidelines and the case law are essentially consistent”). See, e.g., *Coca-Cola Bottling*, 118 F.T.C. at 538-39, 542, 574 (1994) (excluding generic carbonated soft drinks and all non-carbonated soft drinks from a brand carbonated soft drink market); *Olin Corp.*, 113 F.T.C. 400, 604 (1990) (excluding liquid pool sanitisers from a dry pool sanitiser market); *United States v. Gillette Co.*, 828 F. Supp. 78, 83-84 (D.D.C. 1993) (separating premium writing instruments from other lower-priced writing instruments); *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1075 (D.D.C. 1997) (separating office superstores from other sellers of office supplies; “the mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes.”). Cf. HOVENKAMP at 4-41 (explaining that pencils and pens would not be deemed effective substitutes if pen sellers are able to raise prices more than 10 percent above marginal cost without consumers switching to pencils. “In that case, we might still say that pencils are substitutes for pens, but they are not effective substitutes because substitution is not sufficient to hold the price of pens to their cost.”).

¹⁸⁹ See *Archer-Daniels-Midland Co.*, 866 F.2d at 244-45 (explaining that the tools for defining a product market “help evaluate the extent competition constrains market power and are, therefore, indirect measurements of a firm’s market power”); Merger Guidelines, Sec. 1.0 (explaining that the essence of the market definition test is to establish “whether a hypothetical monopolist would be in position to exercise market power”); AREEDA ET AL., IIA ANTITRUST LAW ¶ 531a (1995) (“finding the relevant [product] market and its structure is not a goal in itself but a surrogate for market power”). Cf. *FTC v. Indiana Fed’n of Dentists*, 476 US 447, 460-61 (1986) (holding that evidence of actual adverse effects on competition -- such as output reductions or price increases -- can obviate the need for inquiry into market definition or market power).

¹⁹⁰ *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (per curiam) (explaining that monopoly power can be shown by “direct proof . . . of an ability to . . . profitably raise prices substantially above the competitive level”).

¹⁹¹ *Motion Picture Patents v. Universal Film Mfg Co.*, 243 US 502, 510 (1917) (describing patent law as protecting “the monopoly of that which he has invented”); but see *Cabrice Corp. of Am. v. American Patent Dec. Corp.*, 283 US 27 (1931) (stating that a patent confers only a “limited monopoly”).

¹⁹² See *Jefferson Parish Hospital District No. 2 v. Hyde*, 466 US 2, 16 (1984) (holding that if a product is protected by a patent, “it is fair to presume that the inability to buy the product elsewhere gives the seller market power”); *Standard Oil Co. v. United States*, 337 US 293, 307 (1949) (stating that a “patent, . . . although in fact there may be many competing substitutes for the patented article, is at least *prima facie* evidence of market control”). Lower courts have adopted varying approaches in specific cases. Compare *Abbott Laboratories v. Brennan*, 952 F.2d 1346, 1354-55 (Fed. Cir. 1991) (no presumption of market power from intellectual property right) with *Digidyne Corp. v. Data General Corp.*, 734 F.2d 1336, 1341-42 (9th Cir. 1984) (requisite economic power presumed from copyright).

¹⁹³ *Jefferson Parish Hospital District No. 2 v. Hyde*, 466 US 2, at 37 n.7 (O’Connor, J., concurring) (1984); accord *Northern Pacific v. United States*, 356 US 1, 10 n.8 (1958) (“It is common knowledge that a patent does not always confer a monopoly over a particular commodity. Often the patent is limited to a unique form or

According to the Antitrust Guidelines for the Licensing of Intellectual Property:

The Agencies will not presume that a patent, copyright, or trade secret necessarily confers market power upon its owner. Although the intellectual property right confers the power to exclude with respect to the specific product, process, or work in question, there will often be sufficient actual or potential close substitutes for such product, process, or work to prevent the exercise of market power.¹⁹⁴

In abuse of dominant position cases involving pharmaceuticals, US antitrust authorities almost always define markets as consisting of a single product as defined by active ingredient, corresponding to the Anatomic Therapeutic Classification (ATC) level 5.¹⁹⁵ These conclusions are often based on findings that other medicines in the same ATC3 or ATC4 therapeutic class are “different in terms of chemical composition, safety, efficacy, and side effects” as well as evidence showing “little price sensitivity” between the potential substitute products.¹⁹⁶

US antitrust authorities sometimes define the market as consisting only of a specific formulation of a single product.¹⁹⁷ For example, in *In the Matter of Biovail Corporation*, the

improvement of the product and the economic power resulting from the patent privileges is slight.”); *see also* *SCM Corp. v. Xerox*, 645 F.2d 1195, 1203 (2d Cir. 1981) (stating that a patented product often “represents merely one of many products that effectively compete in a given product market”).

¹⁹⁴ At Section 2.2. *Cf.* HERBERT HOVENKAMP, MARK JANIS AND MARK LEMLEY, *IP AND ANTITRUST VOL. 1*, 4-8 (2002) (“The intellectual property laws do not confer any monopoly . . . but only the right to exclude others from producing the good, expression or symbol covered by the intellectual property interest. This right is a property right that is not different in principle from other property rights. Ownership of a common law possessory interest in property ordinarily grants a power to exclude.”); *cf.* OLIVER HOLMES, JR., *THE COMMON LAW* 246 (1881) (describing common law property rights including right to exclude); Oliver Holmes, Jr., *Possession*, 12 *Am. L. Rev.* 688 (1878) (same).

¹⁹⁵ The ATC system has five levels of classification. The fourth level is classified according to subtherapeutic group, and the fifth level is chemical substances themselves.

¹⁹⁶ *See* Federal Trade Commission Complaint, *In the Matter of Abbott Laboratories and Geneva Pharmaceuticals, Inc.* Docket No. C-3946, 2000, <http://www.ftc.gov/os/2000/03/abbottcmp.htm> (defining relevant market as terazosin hydrochloride because “Other drugs are not effective substitutes for terazosin HCL because they are different in terms of chemical composition, safety, efficacy, and side effects. In addition, there is little price sensitivity between terazosin HCL and non-terazosin HCL products.”); Federal Trade Commission Complaint, *In the Matter of Hoechst Marion Rousell, Inc., Carderm Capital L.P., and Andrx Corporation*, Docket No. 9293, 2000, <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm> (defining relevant product market as once-a-day diltiazem because “Other calcium channel blockers are not acceptable substitutes for diltiazem for several reasons, including, inter alia, the differences in efficacy and side effects, and the risks associated with switching patients from one calcium channel blocker to another. In addition, narrower relevant product markets may be contained within the market for once-a-day diltiazem products.”); Federal Trade Commission Complaint, *In the Matter of Asahi Chemical Industry Co., Ltd.*, 2000 <http://www.ftc.gov/os/2000/12/fmcasahicomplaint.htm> (“Other binders are not acceptable substitutes for pharmaceutical MCC for several reasons, including differences in quality, consistency, performance, efficacy, and stability. Entry into the relevant market is difficult and time-consuming.”).

¹⁹⁷ *See* Federal Trade Commission Complaint, *FTC v. Mylan Laboratories, Inc., Cambrex Corporation, Profarmaco S.R.L., and Gyma Laboratories of America, Inc.*, FTC File No. X990015 (District for the District of Columbia), 1999, <http://www.ftc.gov/os/1999/02/mylanamencmp.htm> (“There are four relevant markets: (1) the market for generic lorazepam tablets approved for sale in the United States; (2) the market for generic clorazepate tablets approved for sale in the United States; (3) the market for lorazepam API approved for sale in the United States; and (4) the market for clorazepate API approved for sale in the United States.”); Federal Trade Commission Complaint, *In the Matter of Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation*, Docket No. 9297, 2001, www.ftc.gov/os/2001/04/scheringpart3cmp.pdf

Federal Trade Commission (FTC) defined the relevant product market as Tiazac, a diltiazem-based prescription drug taken once a day to treat high blood pressure (hypertension) and chronic chest pain (angina), and generic bioequivalent versions of Tiazac. While acknowledging therapeutic substitutes, the FTC argued that they did not constrain Biovail's pricing in the way generic competition would:

In addition to Tiazac, other therapeutic agents can be used to treat high blood pressure and chronic chest pain, including several branded and generic formulations of once-a-day diltiazem, but these other therapeutic agents do not significantly constrain Tiazac's pricing. In contrast, entry of a generic bioequivalent version of Tiazac likely would result in a significant, immediate decrease in the sales of branded Tiazac, and lead to a significant reduction in the average market price paid for Tiazac and its generic bioequivalents.¹⁹⁸

In a case involving Bristol-Myers Squibb, the FTC defined the relevant product market as the market for buspirone products, which consists of Bristol-Myers Squibb's product BuSpar and generic bioequivalent versions of BuSpar. In reaching this determination, the FTC made parallel arguments to the Biovail case:

65. Entry of generic buspirone products significantly and immediately decreased BMS's BuSpar sales and market share, and led to a substantial reduction in the average market price paid for buspirone products. Before generic entry, BMS's US BuSpar sales were over \$600 million. In the year after generic entry, BMS's US BuSpar sales declined by more than 50%.

66. Because of this competitive relationship between BuSpar and its generic bioequivalent drug rivals, such products comprise a distinct relevant product market for antitrust purposes. Other therapeutic agents can be used to treat anxiety, but the presence of these therapeutic agents is not sufficient to prevent the anticompetitive effects from BMS's conduct.¹⁹⁹

In merger cases, US practice is to scrutinise closely overlapping markets between merger firms. Current trends require divestiture of overlapping products in narrowly defined product and geographic markets, where post-merger combinations would give the newly merged firm market power, or expand the existing market power of one of the firms. The general approach has led the US antitrust authorities to assess markets in merger cases on a case-by-case basis, without presumptive reliance on therapeutic groups or other general product

(asserting that the "relevant product markets are the manufacture and sale of all potassium chloride supplements approved by the FDA [Food and Drug Administration], and narrower markets contained therein, including manufacture and sale of 20 milliequivalent extended-release potassium chloride tablets and capsules"); *but see* Initial Decision, *In the Matter of Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation*, Docket No. 9297, 2002 www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf (ruling of administrative law judge that the relevant market was for any presentation of potassium chloride supplements).

¹⁹⁸ Federal Trade Commission Complaint, *In the Matter of Biovail Corporation*, Docket No. C-4060, paragraphs 19-20, 2002, <http://www.ftc.gov/os/2002/04/biovailcomplaint.htm>

¹⁹⁹ Federal Trade Commission Complaint, *In the Matter of Bristol-Myers Squibb Company*, Docket No. C-4076, 2003, <http://www.ftc.gov/os/caselist/bristolmyerscomp.pdf>

groupings. In practice, the authorities generally find product markets to be defined by therapeutic group, though whether this tracks ATC3 or ATC4 varies.²⁰⁰

In some pharmaceutical merger cases, the US antitrust authorities have defined relevant product markets as consisting of a single product. In the Glaxo-Wellcome/SmithKline Beecham merger, for example, the FTC identified nine separate markets, varying across therapeutic categories, and in one instance composed of a single drug.²⁰¹ In the Ciba-Geigy/Sandoz-Novartis merger, the FTC defined relevant markets as a) a specific gene therapy to meet a specific therapeutic purpose (analogous to defining a single drug as the product market), b) all gene therapies to serve a particular therapeutic purpose (similar to defining the product market as a therapeutic class, though this definition is narrower than therapeutic class and c) all gene therapies.²⁰²

²⁰⁰ See Federal Trade Commission Complaint, *In the Matter of Amgen Inc. and Immunex Corporation*, Docket No. C-4056, 2002, <http://www.ftc.gov/os/2002/07/amgencomplaint.pdf> (determining relevant markets to be research, development, manufacture and sale of Neutrophil Regeneration Products, TNF Inhibitors and IL-1 Inhibitors; determined relevant product markets be research, development, manufacture and sale of Factor VIII Inhibitor Treatments and Fibrin Sealant); Federal Trade Commission Complaint, *In the Matter of Baxter International*, Docket No. C-3726, 1997, <http://www.ftc.gov/os/1997/03/c3726cmp.htm> and Federal Trade Commission Complaint, *In the Matter of Baxter International Inc., and Wyeth*, Docket No. C-4068, 2002, http://www.ftc.gov/os/2002/12/baxter_wyethcomplaint.pdf (determining relevant product markets to be generic versions of injectable pharmaceuticals, Pancuronium, Vecuronium, Metoclopramide, Propofol and New Injectable Iron Replacement Therapies); Federal Trade Commission Complaint, *In the Matter of Pfizer Inc., and Pharmacia Corporation*, Docket No. C-4075, 2002, <http://www.ftc.gov/os/2003/04/pfizercmp.htm> (determining relevant product markets to be: the research, development, manufacture and sale of extended release prescription drugs for the treatment of Overactive Bladder, replacement therapy, prescription drugs for the treatment of erectile dysfunction, prescription drugs for the treatment of canine arthritis, prescription drugs for the treatment of dry cow mastitis, prescription drugs for the treatment of lactating cow mastitis; and the manufacture and sale of over-the-counter hydrocortisone creams and ointments, over-the-counter motion sickness medication, and over-the counter cough drops); Federal Trade Commission Complaint, *In the Matter of Roche Holding Ltd*, Docket No. C-3809, 1998, <http://www.ftc.gov/os/1998/02/9710103.cmp.htm> (defining the relevant market as the research, development, manufacture and sale of Cardiac Thrombolytic Agents and diagnostic reagents used for workplace tests for any drug of abuse); Federal Trade Commission Complaint, *In the Matter of Zeneca Group PLC*, Docket No. C-3880, 1999, <http://www.ftc.gov/os/1999/03/zenecacmp.htm> (defining the relevant market as consisting of long-acting local anaesthetics).

²⁰¹ The distinct markets were: 5HT-3 antiemetic drugs, which are administered to cancer patients undergoing chemotherapy and radiation treatments to reduce nausea and vomiting, and were defined as a separate market from older antiemetic products; Ceftazidime, an injectable antibiotic, defined as a market distinct from all other products, including other antibiotics to treat hospitalised patients at risk for pseudomonas infection; oral and intravenous antiviral drugs to treat herpes; topical antiviral cold sore (herpes) drugs; prophylactic herpes vaccines; over-the-counter Histamine-2 blocker acid relief products (H-2 blockers); topoisomerase I inhibitor drugs used to treat ovarian, non-small cell lung, colorectal and other types of solid-tumour cancers; migraine treatment drugs; and irritable bowel syndrome drugs. Federal Trade Commission Complaint, *In the Matter of Glaxo Wellcome plc, and SmithKline Beecham plc*, Docket No. C-3990, 2000, <http://www.ftc.gov/os/2000/12/glaxosmithklinecmp.pdf>.

²⁰² “One relevant line of commerce in which to analyse the effects of the proposed merger is gene therapy technology and R&D of gene therapies, including ex vivo and in vivo gene therapy. Specific gene therapy product markets, in which the effects of the proposed merger may be analysed include the research, development, manufacture and sale of:

- (a) herpes simplex virus-thymidine kinase ("HSV-tk") gene therapy for the treatment of cancer;
- (b) HSV-tk gene therapy for the treatment of graft versus host disease;
- (c) gene therapy for the treatment of haemophilia; and
- (d) chemoresistance gene therapy.”

The FTC also defined corn herbicides and flea control products as relevant markets in this case. Federal Trade Commission Complaint, *In the Matter of Ciba-Geigy Limited, Ciba-Geigy Corporation, Chiron*

At bottom, US antitrust authorities have a great deal of flexibility in defining markets. Market definition for antitrust purposes may appropriately involve both wider and narrower markets. In the case of mergers, overly narrow market definitions may exclude a product that has a price competitive effect on another from consideration, and thus enable merged product lines that create or enhance market power on the part of the newly created firm. This may be the case, even though each of the products are able to exert market power and may be considered product markets in their own right. In abuse of dominance cases, by contrast, the consistent practice is to define markets very narrowly.

3.2.1.2 Illegal Refusals to Deal under US Law

Once monopoly power is established, the substantive provisions of the Sherman Act become applicable. Generally, the Sherman Act does not impose a duty on monopolies to deal with competitors. But a series of Supreme Court and lower court decisions have found violations of the Act where (1) the refusal to deal is “exclusionary”, “anticompetitive” or “predatory” and (2) the defendant fails to justify the refusal with procompetitive business justifications.²⁰³ The Sherman Act prohibits dominant firms from “attempting to exclude rivals on some basis other than efficiency”.²⁰⁴

The situations in which the Supreme Court has found a lack of sufficient procompetitive justification for a refusal to deal with a competitor are varied. Since *United States v. Colgate & Co.*, 250 US 300 (1919), it has been clear that a monopolist cannot refuse to deal with a competitor for the “purpose to create or maintain a monopoly”.²⁰⁵ Based on this early precedent, the Court affirmed violations of the Sherman Act where trial courts reasonably concluded that a refusal to deal was “in furtherance of a purpose to monopolise” because no other legitimate business justification adequately explained a refusal to deal that harmed a competitor.²⁰⁶

In *Eastman Kodak v. Southern Photo Materials Co.*, the Court held that Eastman Kodak violated the Sherman Act by refusing to sell supplies to a retailer at wholesale prices, with no legitimate justification, after the retailer resisted an effort by Kodak to purchase the distributor.²⁰⁷

Corporation, Sandoz Ltd., Sandoz Corporation, and Novartis AG, Docket No. C-3725, 1997, <http://www.ftc.gov/os/1997/04/c3725cmp.htm>.

²⁰³ *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 US 585, 605 (1985).

²⁰⁴ *Id.*

²⁰⁵ The Court explained:

In the absence of any purpose to create or maintain a monopoly, the act does not restrict the long recognized right of a trader or manufacturer engaging in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal; and, of course, he may announce in advance the circumstances under which he will refuse to sell.

United States v. Colgate & Co., 250 US 300, 307 (1919).

²⁰⁶ *Eastman Kodak v. Southern Photo Materials Co.*, 273 US 359, 375 (1927).

²⁰⁷ 273 US at 375. The Court explained:

[T]he defendant contends not only that there was no direct evidence as to the purpose of such refusal overcoming the presumption that it was a lawful one, but that such refusal was justified by the fact that the plaintiff had previously undertaken to handle the goods of another manufacturer under a preferential contract. Aside from the plaintiff's contention that this contract related merely to goods

In *United States v. Griffith*, 334 US 100 (1948), the Court held that the defendant's use of a monopoly in theatres in some cities to obtain exclusive movie distribution privileges in other cities was properly found to be anticompetitive. The Court explained:

The anti-trust laws are as much violated by the prevention of competition as by its destruction. It follows a fortiori that the use of monopoly power, however lawfully acquired, to foreclose competition, to gain a competitive advantage, or to destroy a competitor, is unlawful.²⁰⁸

In *Lorain Journal Co. v. United States*, 342 US 143 (1951), the Supreme Court affirmed Sherman Act liability for a dominant newspaper that refused to sell space to customers who advertised on a new radio station, with the intent to achieve "the complete destruction" of the radio station and re-establish the paper's "pre-1948 substantial monopoly".²⁰⁹ The Court explained:

The publisher claims a right as a private business concern to select its customers and to refuse to accept advertisement from whomever it pleases. We do not dispute that general right. "But the word 'right' is one of the most deceptive of pitfalls; it is so easy to slip from a qualified meaning in the premise to an unqualified one in the conclusion. Most rights are qualified."²¹⁰ The right claimed by the publisher is neither absolute nor exempt from regulation. Its exercise as a purposeful means of monopolizing interstate commerce is prohibited by the Sherman Act.²¹¹

The fullest discussion of the refusal to deal doctrine by the Supreme Court occurs in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 US 585 (1985). In that case, the Court affirmed a finding that a dominant owner of three ski resorts violated the Sherman Act by pulling out of a profitable arrangement to sell combination ski lift tickets with a fourth resort, owned by a smaller competitor. The Court explained that its previous cases had established that a refusal to deal by a firm with market power violates the Sherman Act if it (1) "is fairly characterized as 'exclusionary' or 'anticompetitive' . . . or 'predatory'" and (2) there are no "valid business reasons" for the refusal.²¹²

To determine whether the refusal at issue was anticompetitive, the Court instructed that "it is relevant to consider its impact on consumers and whether it has impaired competition in an

that did not conflict with the sale of those which it had been purchasing from the defendant, it was not shown that the defendant knew of this contract when it refused to sell its goods to the plaintiff. And for this reason, if for no other, we think that the trial court rightly declined to charge the jury to the effect that such taking over of other goods by the plaintiff in itself justified the defendant in its refusal to sell to the plaintiff. And, although there was no direct evidence-as there could not well be-that the defendant's refusal to sell to the plaintiff was in pursuance of a purpose to monopolize, we think that the circumstances disclosed in the evidence sufficiently tended to indicate such purpose, as a matter of just and reasonable inference, to warrant the submission of this question to the jury. . . . And the weight of the evidence being in such case exclusively a question for the jury, its determination is conclusive upon this question of fact.

²⁰⁸ 334 US at 107 (internal citation omitted)

²⁰⁹ *Lorain Journal*, 343 US at 150, 153.

²¹⁰ *American Bank & Trust Co. v. Federal Reserve Bank*, 256 US 350, 358 (Justice Holmes).

²¹¹ *Lorain Journal*, 343 US at 155.

²¹² 472 US at 605 (internal quotation marks and citations committed).

unnecessarily restrictive way.”²¹³ The Court affirmed that the refusal to continue the multi-area ticket was anticompetitive because consumers lost access to a “superior quality . . . all-Aspen ticket” that “provided convenience and flexibility”. It also noted that the smaller competitor found the development of a comparable product “prohibitively expensive” and experienced a steady decline in market share as a result of the discontinuation of the all-Aspen ticket.²¹⁴

Turning to the defendant’s justifications, the Court substantively analyzed each proffered reason for discontinuing the ticket, finding none of them adequate to defeat the jury’s determination that its conduct was not justified by any normal business purpose. The Court explained:

Ski Co. was apparently willing to forgo daily ticket sales both to skiers who sought to exchange the coupons contained in Highlands' Adventure Pack, and to those who would have purchased Ski Co. daily lift tickets from Highlands if Highlands had been permitted to purchase them in bulk. The jury may well have concluded that Ski Co. elected to forgo these short-run benefits because it was more interested in reducing competition in the Aspen market over the long run by harming its smaller competitor.

That conclusion is strongly supported by Ski Co.'s failure to offer any efficiency justification whatever for its pattern of conduct.²¹⁵

The Supreme Court specifically rejected several proffered justifications, including claims by the dominant firm that usage could not be properly monitored, that the coupons were administratively cumbersome and that it desired to disassociate itself from what it considered the inferior skiing services offered at the smaller competitor. To the latter point, the Court countered that “[t]he all-Aspen ticket based on usage . . . allowed consumers to make their own choice on these matters of quality.”²¹⁶ The Court concluded:

The refusal to accept the Adventure Pack coupons in exchange for daily tickets was apparently motivated entirely by a decision to avoid providing any benefit to Highlands even though accepting the coupons would have entailed no cost to Ski Co. itself, would have provided it with immediate benefits, and would have satisfied its potential customers. Thus the evidence supports an inference that Ski Co. was not motivated by efficiency concerns and that it was willing to sacrifice short-run benefits and consumer goodwill in exchange for a perceived long-run impact on its smaller rival.²¹⁷

In the most recent US Supreme Court case involving the refusal to deal doctrine, *Eastman Kodak v. Image Technical Services*, 504 US 451 (1992), Kodak restricted the sale of patented and unpatented replacement parts to independent service. The Supreme Court repeated its previous descriptions of the doctrine, explaining that “[l]iability turns . . . on whether ‘valid

²¹³ 472 US at 605.

²¹⁴ 472 US at 605-608.

²¹⁵ 472 US at 608.

²¹⁶ 472 US at 610.

²¹⁷ 472 US at 610-11.

business reasons’ can explain Kodak’s actions.”²¹⁸ Echoing *Lorain Journal and Aspen Skiing*, the Court explained:

It is true that as a general matter a firm can refuse to deal with its competitors. But such a right is not absolute; it exists only if there are legitimate competitive reasons for the refusal.²¹⁹

3.2.1.3 United States Essential Facilities Doctrine

Lower federal courts in the US have developed a subspecies of the refusal to deal doctrine involving “essential facilities”. Courts have recognized a claim under the Sherman Act where a dominant firm has

- (1) refused access to an “essential facility” and
- (2) there are not valid procompetitive business justifications for the refusal.

“A company which has monopoly power over an essential facility may not refuse to make the facility available to others where there is no legitimate business reason for the refusal.”²²⁰

The essential facility doctrine is often described as evolving from the Supreme Court’s decision in *United States v. Terminal Railroad Association*, 224 US 383 (1912), although the Supreme Court has never used the term “essential facility”.²²¹ In *Terminal Railroad*, the Supreme Court held that an association of railroads that owned all of the key rail terminals, bridges and switching yards in St. Louis illegally restrained trade by refusing to deal with nonmembers. The decision was driven by a view that promotion of the “the greatest public utility” is the overriding goal of the Sherman Act. The Court found that “the situation at St. Louis is most extraordinary” because the “physical or topographical condition peculiar to the locality” would not accommodate multiple terminals. Thus, the “prime justification for a unified system of terminals” was also “a most obvious reason why such a unified system is an obstacle, a hindrance, and a restriction upon interstate commerce, unless it is the impartial agent of all”.²²²

²¹⁸ 504 US at 483.

²¹⁹ 504 US at 483 n.32. Because the factual determination of whether Kodak’s decisions were based on legitimate competitive reasons rather than a willful attempt to monopolise is for the jury in the US system and a trial had not yet begun, the Court remanded for further proceedings in which Kodak was found to have violated the Sherman Act. See *Image Technical Servs. Inc. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997) (affirming trial court’s finding of liability).

²²⁰ *City of Anaheim v. So. Cal. Edison*, 955 F.2d 1373, 1379 (9th Cir. 1992).

²²¹ One may trace elements of the doctrine back further to common law duties of transportation and other essential service providers to deal with all on equal terms. Cf CHARLES M. HAAR AND DANIEL W. FESSLER, *THE WRONG SIDE OF THE TRACKS: REVOLUTIONARY REDISCOVERY OF THE COMMON LAW TRADITION OF FAIRNESS IN THE STRUGGLE AGAINST INEQUALITY* (New York: Simon And Schuster, 1986); Gillette, Clayton *Equality and Variety in the Delivery of Municipal Services* 100 Harv. L. Rev. 946 (1987) (same).

²²² 224 US at 405. The Court cited the testimony of an experienced railroad engineer that unification of terminals in any city “may be of the greatest public utility and of immeasurable advantage to commerce” but that “such a terminal company should be the agent of every company, and, furthermore, that its service should not be for profit or gain. . . . This, he thinks, will serve the greatest possible economy, and will give the most efficient service without discrimination.” *Id.* at 405-06.

If, as we have already said, the combination of two or more mere terminal companies into a single system does not violate the prohibition of the statute against contracts and combinations in restraint of interstate commerce, it is because such a combination may be of the greatest public utility. But when, as here, the inherent conditions are such as to prohibit any other reasonable means of entering the city, the combination of every such facility under the exclusive ownership and control of less than all of the companies under compulsion to use them violates both the first and second sections of the act, in that it constitutes a contract or combination in restraint of commerce among the states, and an attempt to monopolize commerce among the states which must pass through the gateway at St. Louis.²²³

Rather than dissolve the association as the government had requested, the Court explained that an alteration of the terminal agreement to allow all competitors to use the facility would best “preserve to the public a system of great public advantage.”²²⁴ It, therefore, ordered the association to deal with nonmembers “upon such just and reasonable terms and regulations as will . . . place every such company upon as nearly an equal plane as may be.”²²⁵

The second Supreme Court case often cited as using an essential facilities theory of antitrust liability is *Otter Tail Power Co. v. United States*²²⁶. In that case, a utility with market power over wholesale electricity distribution, that also supplied retail service, refused to sell or transmit power to towns that wanted to replace it as the retail distributor. The Court noted that “[i]nterconnection with other utilities is frequently the only solution” to towns wishing to purchase power at wholesale and that “[t]here were no engineering factors that prevented Otter Tail from selling power at wholesale to those towns . . . or wheeling the power” over its lines.²²⁷

In holding that the dominant firm violated the Sherman Act, the Court rejected the defendant’s justification that “without the weapons which it used, more and more municipalities will turn to public power and Otter Tail will go downhill.”²²⁸ The Court explained:

The argument is a familiar one. . . . We said [in *United States v. Arnold, Schwinn & Co.*]: “The promotion of self-interest alone does not invoke the rule of reason to immunize otherwise illegal conduct.”

The same may properly be said of s 2 cases under the Sherman Act. That Act assumes that an enterprise will protect itself against loss by operating with superior service, lower costs, and improved efficiency. Otter Tail’s theory collided with the Sherman Act as it sought to substitute for competition anticompetitive uses of its dominant economic power.²²⁹

²²³ 224 US at 409.

²²⁴ 224 US at 410.

²²⁵ 224 US at 411.

²²⁶ 410 US 366 (1973).

²²⁷ 224 US at 378.

²²⁸ 410 US at 380.

²²⁹ 410 US at 380.

The Court noted that a legitimate justification for denying access to competitors may be that dealing with competitor would “threaten its capacity to serve adequately the public.”²³⁰ But it affirmed the district court’s finding that Otter Tail’s complaints in this regard were not supported by the record. The Court, therefore, affirmed the lower court order that the utility serve the retail municipalities at “rates which are compensatory”.²³¹

The term “essential facility” was coined in Neale’s antitrust treatise to describe the outcome in Supreme Court cases including *Terminal Railroad* and *Otter Tail*.²³² The term first appeared in antitrust case law in *Hecht v. Pro Football, Inc.*, 570 F.2d 982 (D.C. Cir. 1977), a case dealing with a refusal of the Washington Redskins football team to allow a potential competitor use its stadium. Quoting Neale’s treatise, the D.C. Circuit stated:

The essential facility doctrine, also called the ‘bottleneck principle,’ states that ‘where facilities cannot practicably be duplicated by would be competitors, those in possession of them must allow them to be shared on fair terms. It is an illegal restraint of trade to foreclose the scarce facility.’ . . . To be “essential” a facility need not be indispensable; it is sufficient if duplication of the facility would be economically infeasible and if denial of its use inflicts a severe handicap on potential market entrants. Necessarily, this principle must be carefully delimited: the antitrust laws do not require that an essential facility be shared if such sharing would be impractical or would inhibit the defendant’s ability to serve its customers adequately.²³³

Subsequently, the Seventh Circuit applied the essential facility doctrine in *MCI Communications Corp. v. AT&T*, 708 F.2d 1081 (7th Cir. 1982), to order the American Telephone and Telegraph monopoly to allow a new competitor to connect its lines to the nationwide telephone network. The court explained:

A monopolist’s refusal to deal under these circumstances is governed by the so-called essential facilities doctrine. Such a refusal may be unlawful because a monopolist’s control of an essential facility (sometimes called a “bottleneck”) can extend monopoly power from one stage of production to another, and from one market into another. Thus, the antitrust laws have imposed on firms controlling an essential facility the obligation to make the facility available on non-discriminatory terms.²³⁴

Citing *Hecht*, *Terminal Railroad*, and *Otter Tail*, the Seventh Circuit described the case law as setting four elements necessary to establish liability under the essential facilities doctrine:

- (1) control of the essential facility by a monopolist;

²³⁰ 410 US at 381.

²³¹ 410 US at 375, 382.

²³² NEALE, *THE ANTITRUST LAW OF THE UNITED STATES* 67 (2d ed. 1970).

²³³ *Hecht*, 570 F.2d at 992-93 & n.36 (citations omitted) (holding: “if the jury found (1) that use of RFK stadium was essential to the operation of a professional football team in Washington; (2) that such stadium facilities could not practicably be duplicated by potential competitors; (3) that another team could use RFK stadium in the Redskins’ absence without interfering with the Redskins’ use; and (4) that the [exclusivity provision] prevented equitable sharing of the stadium by potential competitors, then the jury must find the [provision] to constitute a contract in unreasonable restraint of trade”).

²³⁴ 708 F.2d at 1132.

- (2) a competitor's inability practically or reasonably 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.²³⁵

The court in MCI concluded that a key factor was that it was “technically and economically feasible for AT&T to have provided the requested interconnections,” and therefore affirmed liability under the Act.²³⁶ The Seventh Circuit’s description of the elements of the essential facility doctrine has been widely used by other courts applying the doctrine.

(1) *Control of an essential facility*

A facility will be held to be essential “if control of the facility carries with it the power to eliminate competition.”²³⁷ Access to the facility must be more than “merely helpful”,²³⁸ although “[t]o be ‘essential’ a facility need not be indispensable; it is sufficient if duplication of the facility would be economically infeasible and if denial of its use inflicts a severe handicap on potential market entrants.”²³⁹

Although the doctrine was developed to deal with access to physical facilities like railroad infrastructure, stadiums and telephone lines, courts have not restricted the term “facility” to tangible assets. As one district court noted in a case involving telephone directory information, “there is no reason why it could not apply, as in this case, to information wrongfully withheld. The effect in both situations is the same: a party is prevented from sharing in something essential to compete.”²⁴⁰

²³⁵ 708 F.2d at 1132-33

²³⁶ The court explained:

AT&T had complete control over the local distribution facilities that MCI required. The interconnections were essential for MCI to offer FX and CCSA service. The facilities in question met the criteria of “essential facilities” in that MCI could not duplicate Bell’s local facilities. Given present technology, local telephone service is generally regarded as a natural monopoly and is regulated as such. It would not be economically feasible for MCI to duplicate Bell’s local distribution facilities (involving millions of miles of cable and line to individual homes and businesses), and regulatory authorization could not be obtained for such an uneconomical duplication.

Finally, the evidence supports the jury’s determination that AT&T denied the essential facilities, the interconnections for FX and CCSA service, when they could have been feasibly provided. No legitimate business or technical reason was shown for AT&T’s denial of the requested interconnections. MCI was not requesting preferential access to the facilities that would justify a denial. MCI produced sufficient evidence at trial for the jury to conclude that it was technically and economically feasible for AT&T to have provided the requested interconnections, and that AT&T’s refusal to do so constituted an act of monopolization.

708 F.2d at 1133 (citations omitted).

²³⁷ *City of Anaheim*, 955 F.2d at 1380 n.5 (quoting *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 544 (9th Cir. 1991)).

²³⁸ *America Online, Inc. v. GreatDeals.net*, 49 F. Supp. 2d 851, 862 (E.D. Va. 1999).

²³⁹ *Hecht*, 570 F.2d at 992-93.

²⁴⁰ *BellSouth Adver. & Publishing Corp. v. Donnelley Info. Publ’g*, 719 F. Supp. 1551, 1568 (S.D. Fla. 1988), rev’d on other grounds, 999 F.2d 1436 (11th Cir. 1993).

(2) *Inability practically or reasonably to duplicate the essential facility*

Related to the question of the essential nature of the facility,²⁴¹ it must be shown that the facility cannot be duplicated through practical and reasonable means. Courts have held that the “inquiry into the practicability of duplicating the facility should consider economic, regulatory and other concerns.”²⁴² Courts have explained that “[a]s the word ‘essential’ indicates, a plaintiff must show more than inconvenience, or even some economic loss”;²⁴³ the plaintiff must have “no realistic, economically practical alternative means” of obtaining the needed input.²⁴⁴

The question frequently turns on the expense of duplication, since almost any facility can be duplicated if resources are unlimited. Thus, courts have found that stadiums are often essential facilities, despite the potential ability to build a new one, because stadiums are not “duplicable without an expenditure . . . unreasonable in light of the size of the transaction”.²⁴⁵

(3) *Denial of the use of the facility*

Courts have held that “there need not be an outright refusal to deal in order to find that denial of an essential facility occurred. It is sufficient if the terms of the offer to deal are unreasonable.”²⁴⁶

Following the rule that a refusal to deal may be found based on unreasonable dealing, the Second Circuit affirmed liability of a large rail operator for denial of an essential facility where access would be granted to competitors “only if its profit [from the access fee], matched its profit on the route where it was the sole carrier”.²⁴⁷ Similarly, in *Fishman v. Wirtz*, 807 F.2d 520 (7th Cir. 1986), the Seventh Circuit held that a stadium owner refused access to its essential facility by demanding onerous contract terms that were not standard in other agreements. The Court concluded: “this offer did not show that Wirtz was willing to deal with IBI on non-discriminatory terms”; “Agreeing to deal on unreasonable terms is merely a type of refusal to deal.”

(4) *Feasibility of providing the facility, including legitimate justifications*

When considering the feasibility of providing access, US courts consider technical and economic feasibility as well as whether there is a legitimate business justification for refusing

²⁴¹ *City of Anaheim v. So. Cal. Edison*, 955 F.2d 1373, 1380 (9th Cir. 1992) (noting that an inability to duplicate the facility “is effectively part of the definition of what is an essential facility in the first place”).

²⁴² *Florida Fuels, Inc. v. Blecher Oil Co.*, 717 F. Supp. 1528, 1533 (S.D. Fla. 1989) (“Although expensive in absolute terms, the cost of duplication may be reasonable in light of transactions that would be duplicated and the possible profits to be gained.”).

²⁴³ *Twin Labs., Inc. v. Weider Health & Fitness*, 900 F.2d 566, 570 (2nd Cir. 1990).

²⁴⁴ *City of Malden*, 887 F.2d at 163 n.6 (case involving access to wholesale electricity); *cf. Corsearch, Inc. v. Thomson & Thomson*, 792 F. Supp. 305 (S.D.N.Y. 1992) (holding that computer database was not an essential facility because plaintiff could build own database at an affordable cost).

²⁴⁵ *Fishman v. Estate of Wirtz*, 807 F.2d 520, 540 (7th Cir. 1986).

²⁴⁶ *Delaware & Hudson Ry. Co. v. Consolidated Rail Corp.*, 902 F.2d 174, 179-180 (2d Cir. 1990).

²⁴⁷ 902 F.2d at 177 (explaining: “The make or buy policy was intended to assure that Conrail would receive the same contribution for any carriage in which it participated, whether it was the short or long haul carrier. Accordingly, under its new policy, Conrail demanded a contribution of \$10,000 for the Harrisburg-Lancaster short haul route, an increase of 800%.”).

access.²⁴⁸ Where the elements showing that a facility is essential are met, it is normally the defendant's burden to prove that a legitimate business justification motivated the denial.²⁴⁹

Some examples of legitimate motivations mentioned by courts include:

- “sharing would be impractical or would inhibit the defendant's ability to serve its customers adequately”²⁵⁰
- “lack of available space, financial unsoundness, or possibly low business or ethical standards”²⁵¹
- extending access would interfere with the owner's use of the facility²⁵²
- “pursuit of efficiency and quality control”²⁵³

3.2.1.4 Refusals to Licence Intellectual Property

The company claims an absolute and unfettered right to use its intellectual property as it wishes. . . . That is no more correct than the proposition that use of one's personal property, such as a baseball bat, cannot give rise to tort liability. . . Intellectual property rights do not confer a privilege to violate the antitrust laws.

United States v. Microsoft Corp., 253 F.3d 34 (D.C. Cir. 2001).²⁵⁴

We see no . . . reason to inquire into the subjective motivation of Xerox in refusing to sell or licence its patented works. . . .

In re Independent Service Organizations Antitrust Litigation, 203 F.3d 1322, 1327 (Fed. Cir. 2000)

There is a pronounced division between different US courts (and between commentators) on the extent to which a unilateral refusal to deal may be grounds for Sherman Act liability. Positions range from those that profess to apply the same standards to intellectual property as apply to other forms of property to those that appear to grant patent holders immunity from the refusal to deal and essential facility doctrines.

²⁴⁸ See *City of Anaheim v. Southern Calif. Edison Co.*, 955 F.2d 1381 (9th Cir. 1992) (“[T]he fourth element basically raises the familiar question of whether there is a legitimate business justification for the refusal to provide the facility”).

²⁴⁹ James B. Kobak, Jr. *Antitrust Treatment Of Refusals To License Intellectual Property Unilateral Refusal To License Intellectual Property And The Antitrust Laws*, 658 PLI/Pat 603, 609 (2001) (“In the face of exclusionary conduct, the burden to show a valid business justification will rest on the defendant.”); see *Eastman Kodak Co.*, 504 US at 483 86; *Data General Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147, 1183 (1st Cir. 1994).

²⁵⁰ *Hecht v. Pro Football, Inc.*, 570 F.2d 982, 992-93 (D.C. Cir. 1977).

²⁵¹ *Gamco, Inc. v. Providence Fruit & Produce Building, Inc.*, 194 F.2d 484, 487 (1st Cir.).

²⁵² *Hecht v. Pro Football, Inc.*, 570 F.2d 982, 992-93 (D.C. Cir. 1977).

²⁵³ *Data General Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147, 1183 (1st Cir. 1994).

²⁵⁴ (Internal quotation marks and citation omitted). The DC Circuit held that Microsoft breached the Sherman Act through a number of licence restrictions on the use of its software that prevented competitors from promoting rival browsers.

US courts are in general agreement that market power alone does not create an obligation to licence intellectual property to others, just as dominance alone does not require other property holders to grant access to others.²⁵⁵ With little debate in Congress, the US Patent Act was amended in 1988 to clarify that there is no general duty to licence under that Act and that a failure to licence is not a defence to a patent infringement action by the patent holder.²⁵⁶ This Act did not amend the Sherman Act, however, leading the Ninth Circuit to declare that the amendment “does not compel” the “prohibition of all antitrust claims . . . premised on a refusal to license a patent”.²⁵⁷

Federal courts and administrative agencies have applied the refusal to deal doctrine to refusals to licence intellectual property. Under this doctrine, liability turns on the same two factors: (1) the refusal to deal is “exclusionary”, “anticompetitive” or “predatory” and (2) the defendant fails to justify the refusal with procompetitive business justifications.

The First and Ninth Circuits have adopted standards that presume that a refusal to licence intellectual property is based on a legitimate business reason, but allow plaintiffs to rebut that presumption. In *Data General Corp. v. Grumman Systems Support Corp.*, the First Circuit applied the refusal to deal doctrine to a refusal to licence a copyright. The court held that, under the first part of the test, “exclusionary conduct can include a monopolist’s unilateral refusal to license a copyright”. Turning to the question of justification for the conduct, the court concluded that a monopolist’s “desire to exclude others from use of its copyrighted work is a presumptively valid business justification for any immediate harm to consumers.”²⁵⁸ The court reached this conclusion by noting that “a business justification is valid if it relates directly or indirectly to the enhancement of consumer welfare”²⁵⁹ and that “in passing the Copyright Act, Congress itself made an empirical assumption that allowing copyright holders to collect license fees and exclude others from using their works creates a system of incentives that promotes consumer welfare”.²⁶⁰

Despite its deference to the objectives of the Copyright Act, the court concluded that “by no means is a monopolist’s refusal to license a copyright entirely ‘pro-competitive’ within the

²⁵⁵ See *Ethyl Gasoline Corp. v. United States*, 309 US 436, 456-57 (1940) (patent statute gives patent holder right to refuse to licence or sell); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) (“A patent holder [can continue] to exercise his patent's exclusionary power even after achieving commercial success”).

²⁵⁶ The Act states:

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following:

...

(4) refused to license or use any rights to the patent

²⁵⁷ *Image Technical Services v. Eastman Kodak*, 125 F.3d 1195, 1215 n.7 (9th Cir. 1997); see also James Kobac, *Antitrust Treatment of Refusals to License Intellectual Property*, 658 PLI/Pat 603 (2001) (stating that “this misuse statute does not extend to copyrights or, by its terms, to antitrust cases involving patents” and reporting that federal antitrust enforcement agencies consider that the 1988 amendment “only limits the patent misuse defenses available in an infringement case, without necessarily circumscribing the application of antitrust laws”) (citing ABA Section of Antitrust Law, *1995 Federal Antitrust Guidelines for the Licensing of Intellectual Property: Comments & Text* 48 (1996)); Jerome Reichman Expert Report at 37-40 (describing distinctions between misuse and anticompetition claims under US law).

²⁵⁸ 36 F.3d at 1187.

²⁵⁹ 36 F.3d at 1183.

²⁶⁰ 36 F.3d at 1186-87.

ordinary economic framework of the Sherman Act”.²⁶¹ “Wary of undermining the Sherman Act,” the court suggested that the presumption could be rebutted in cases in which imposing antitrust liability is “unlikely to frustrate the objectives of the Copyright Act” to “encourag[e] investment in the creation of desirable artistic and functional works of expression.”²⁶² The court did not find such rebuttal evidence in the case, and therefore rejected liability.

In *Image Technical Servs. Inc. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997), the Ninth Circuit Court of Appeals adopted the rebuttable presumption test of *Data General* for the case, on remand from the Supreme Court, involving a refusal to sell patented parts to independent service operators. The court observed that courts do not normally consider “a monopolist’s unilateral refusal to license a patent as [illegal] ‘exclusionary conduct’,”²⁶³ but that “[t]his basic right of exclusion does have limits.”²⁶⁴ The court explained that “[u]nder current law the defense of monopolization claims will rest largely on the legitimacy of the asserted business justifications” and that “some measure must guarantee that the jury account for the procompetitive effects and statutory rights extended by the intellectual property laws.”²⁶⁵

To assure such consideration, we adopt a modified version of the rebuttable presumption created by the First Circuit in *Data General*, and hold that “while exclusionary conduct can include a monopolist’s unilateral refusal to license a [patent or] copyright,” or to sell its patented or copyrighted work, a monopolist’s “desire to exclude others from its [protected] work is a presumptively valid business justification for any immediate harm to consumers.”²⁶⁶

Applying this standard, the court held that “Kodak may assert that its desire to profit from its intellectual property rights justifies its conduct, and the jury should presume that this justification is legitimately procompetitive.”²⁶⁷ It continued, however, to explain that “this presumption is rebuttable”, including through evidence of pretext – “in other words, [that the proffered reason is] not a genuine reason for Kodak’s conduct.”²⁶⁸ “Neither the aims of intellectual property law, nor the antitrust laws justify allowing a monopolist to rely upon a pretextual business justification to mask anticompetitive conduct.”²⁶⁹ The court concluded that Kodak’s asserted justification for its refusal to deal based on its patent rights were pretext, based on statements of employees and the scope of the refusal which included both patented and unpatented products.²⁷⁰ It accordingly affirmed that Kodak’s refusal to deal was an illegal attempt to monopolize.

²⁶¹ 36 F.3d at 1185.

²⁶² 36 F.3d at 1186-87 and n.64.

²⁶³ 125 F.3d at 1216 (“We find no reported case in which a court has imposed antitrust liability for a unilateral refusal to sell or license a patent or copyright.”).

²⁶⁴ 125 F.3d at 1216.

²⁶⁵ 125 F.3d at 1217-18.

²⁶⁶ 125 F.3d at 1218 (citing *Data General*, 36 F.3d at 1187).

²⁶⁷ 125 F.3d at 1219.

²⁶⁸ 125 F.3d 1219 and 1220 n.12.

²⁶⁹ 125 F.3d at 1219.

²⁷⁰ 125 F.3d at 1219-20:

Evidence regarding the state of mind of Kodak employees may show pretext, when such evidence suggests that the proffered business justification played no part in the decision to act. Kodak's parts manager testified that patents “did not cross [his] mind” at the time Kodak began the parts policy.

The position of the federal antitrust authorities appears less deferential to intellectual property rights. The US Department of Justice and Federal Trade Commission's *Antitrust Guidelines for the Licensing of Intellectual Property* (1995) provide that "[t]he Agencies apply the same general antitrust principles to conduct involving intellectual property that they apply to conduct involving any other form of tangible or intangible property."²⁷¹ An enforcement action settled in 1999 complained that Intel violated the Sherman Act by refusing to grant access to protected information to customers who had sued or threatened to sue Intel. Former FTC Chairman Robert Pitofsky described the Intel case as demonstrating that "US antitrust enforcement agencies will pursue unilateral refusal to deal claims against intellectual property holders when such refusals evidence anticompetitive intent."²⁷² Pitofsky also noted that "claims are just as appropriate when the more stringent standards of the essential facilities doctrine are met" and that "in appropriate cases, the enforcement agencies have imposed mandatory licensing requirements for competitor use of copyrighted systems as a condition of resolving antitrust disputes."²⁷³

The Federal Circuit, which has primary responsibility for litigation under patent law, but not under antitrust laws, has expressed the most deference to intellectual property holders. *In re Independent Service Organizations Antitrust Litigation*, 203 F.3d 1322 (Fed. Cir. 2000) (referred to as *Xerox* hereinafter) involved an independent service organisation (ISO) that alleged that Xerox violated the Sherman Act by setting prices for patented parts higher for ISOs than for end users, with the intent to force ISOs out of the service market. The Federal

Further, no distinction was made by Kodak between "proprietary" parts covered by tooling or engineering clauses and patented or copyrighted products.

...

From this evidence, it is more probable than not that the jury would have found Kodak's presumptively valid business justification rebutted on the grounds of pretext.

²⁷¹ Section 2.2 of the guidelines state:

As with any other tangible or intangible asset that enables its owner to obtain significant supracompetitive profits, market power (or even a monopoly) that is solely a consequence of a superior product, business acumen or historic accident does not violate the antitrust laws. . . . If a patent or other form of intellectual property does confer market power, that market power does not by itself offend the antitrust laws. Nor does such market power impose on the intellectual property owner an obligation to license the use of that property to others. As in other antitrust contexts, however, market power could be illegally acquired or maintained, or, even if lawfully acquired and maintained, would be relevant to the ability of an intellectual property owner to harm competition through unreasonable conduct in connection with such property.

²⁷² Robert Pitofsky, Donna Patterson, Jonathan Hooks, *The Essential Facilities Doctrine Under US Antitrust Law*, 70 Antitrust L. J. 443, 457 (2002); see also James B. Kobak, Jr. *Antitrust Treatment Of Refusals To License Intellectual Property Unilateral Refusal To License Intellectual Property And The Antitrust Laws*, 658 PLI/Pat 603, 639-40 (2001) (citing the Intel enforcement action as demonstrating that US agencies "have challenged an intellectual property holder's absolute right not to licence its intellectual property").

A private suit also arose from the Intel refusals refusing one of its customers -- Intergraph. The district court accepted Intergraph's argument that Intel had breached the Sherman Act under both the refusal to deal and essential facilities doctrines and ordered Intel to provide the requested information. The Federal Circuit overturned the district court's injunction; however, on the basis that the lower court had failed to determine that the two companies were competitors in the same market (Intel did not produce graphical interfaces), thus avoiding the question of whether Intel's refusal to deal was illegal if committed without a valid business justification. See *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346 (Fed. Cir. 1999).

²⁷³ Pitofsky et al., 70 Antitrust L. J. at 457-58. See also F. M. Scherer Expert Report (noting that since the 1940s, the compulsory licensing of patents has been ordered frequently in the settlement of US antitrust cases, including in notable cases involving AT&T, IBM and Xerox).

Circuit rejected the rebuttable presumption test of *Kodak*, and held that a patent owner’s subjective motivation for a refusal to licence is immaterial:

We see no more reason to inquire into the subjective motivation of Xerox in refusing to sell or license its patented works than we found in evaluating the subjective motivation of a patentee in bringing suit to enforce that same right. In the absence of any indication of illegal tying, fraud in the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws. We therefore will not inquire into his subjective motivation for exerting his statutory rights, even though his refusal to sell or license his patented invention may have an anticompetitive effect, so long as that anticompetitive effect is not illegally extended beyond the statutory patent grant.²⁷⁴

Then FTC Chairman Robert Pitofsky expressed concern over the Federal Circuit’s “approach that seems to exalt protection of intellectual property rights” over “the long standing balance between antitrust and intellectual property”²⁷⁵

Traditionally, cases at the intersection between intellectual property and antitrust have been analyzed by examining the impact on economic incentives to innovate and balancing them against anti-competitive effects. . . . An approach that starts from the point that a patent holder does not have to sell or license to anyone, and proceeds from that unchallenged assumption to the rule that it therefore can condition its sales or licenses in any way it sees fit, (with tie in sales as the sole antitrust exception), would be an unwise and unfortunate departure from the traditional approach in this area. I question whether there is reason to believe any such interpretation is necessary to encourage the innovation process.²⁷⁶

In a later article, Pitofsky argued that US antitrust law can and should impose antitrust liability for a monopolist’s refusal to licence intellectual property “as with any other kind of property, tangible or intangible. . . shown to constitute an essential facility i.e., where it meets the four factors set forth in *MCI Communications*”²⁷⁷

²⁷⁴ *Id.* at 1327-28 (citations omitted).

²⁷⁵ Robert Pitofsky, *Challenges of the New Economy: Issues at the Intersection of Antitrust and Intellectual Property*, 68 Antitrust L.J. 913, 921-22 (2001) (footnote omitted).

²⁷⁶ *Id.* at 923-24.

²⁷⁷ Robert Pitofsky, Donna Patterson, Jonathan Hooks, *The Essential Facilities Doctrine Under US Antitrust Law*, 70 Antitrust L. J. 443, 461-62 (2002); *see also id.* at 444 (commenting that the application of the doctrine in cases involving intellectual property is “particularly important” due to the “increase in the number of situations in which the monopolist’s dominance depends on intellectual property.”). For contrary views, *see* Abbott B. Lipsky and J. Gregory Sidak, *Essential Facilities*, 51 Stan. L. Rev. 1187, 1218-220 (1999) (argument by Lipsky, a fellow in Law and Economics at the American Enterprise Institute, and Sidak, a former advisor to the Microsoft Corporation, that essential facilities doctrine “is inconsistent with the exclusivity that is necessary to preserve incentives to create” and therefore is “inherently inconsistent with intellectual property protection”); Hovenkamp et al at 13-18 (advocating for a rule 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 all but the most unusual of circumstances”); *cf.* Jerome Reichman Expert Report at 33 (summarizing the views of some that “the essential facilities doctrine should never be applied to intellectual property except in ‘the most unusual circumstances’” and that “[w]hatever the merits of these arguments in developed economies, a case might logically be made for greater use of this doctrine in developing countries, on fairness grounds”).

3.2.2 European Community²⁷⁸

Article 82 of the European Community (EC) Treaty (formerly Article 86) prohibits “[a]ny abuse by one or more undertakings of a dominant position within the common market”. As under US law, there is no exemption for intellectual property owners, and none has been created by courts. Several recent EC cases have held that, in “exceptional circumstances”, dominant intellectual property holders may violate the EC Treaty by refusing to licence their property.

3.2.2.1 Dominance in the Relevant Market in the European Community

The first step in an abuse of dominance analysis in the EC is to determine whether the defendant possesses market power.

In basic economic terms, market power is the ability of firms to price above marginal cost and for this to be profitable. In competition analysis, market power is determined with the help of a structural analysis of the market, notably the calculation of market shares, which necessitates an examination of the availability of other producers of the same or of substitutable products (substitutability).²⁷⁹

The EC definition of a relevant market is similar to that in the US “A relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products’ characteristics, their prices and their intended use.”²⁸⁰ The conceptual framework for assessing demand substitution is to inquire whether consumers would respond to a small but permanent increase in a product’s price (5-10 percent) by switching to an alternative product in such numbers that it would not be profitable for the firm to raise prices.²⁸¹ If consumers would switch to the alternative product in such a scenario, it is included in the product market for purposes of competition law.

The question to be answered is whether the parties' customers would switch to readily available substitutes or to suppliers located elsewhere in response to an hypothetical small (in the range 5%-10%), permanent relative price increase in the products and areas being considered. If substitution would be enough to make the price increase unprofitable because of the resulting loss of sales, additional substitutes and areas are included in the relevant market. This would be done until the set of products and

²⁷⁸ For expanded analysis, see Oxford Public Interest Lawyers Expert Report A.

²⁷⁹ European Commission's Directorate-General for Competition, *Glossary*, Available at http://europa.eu.int/comm/competition/general_info/m_en.html

²⁸⁰ European Commission, *Commission Notice On the Definition of the Relevant Market for the Purposes of Community Competition Law*, Section II, Published in the Official Journal: OJ C 372 on 9/12/1997. Available at http://europa.eu.int/comm/competition/antitrust/relevma_en.html.

²⁸¹ European Commission, *Commission Notice On the Definition of the Relevant Market for the Purposes of Community Competition Law*, Section II, Published in the Official Journal: OJ C 372 on 9/12/1997. Available at http://europa.eu.int/comm/competition/antitrust/relevma_en.html (“Generally, and in particular for the analysis of merger cases, the price to take into account will be the prevailing market price. This might not be the case where the prevailing price has been determined in the absence of sufficient competition. In particular for investigation of abuses of dominant positions, the fact that the prevailing price might already have been substantially increased will be taken into account.”).

geographic areas is such that small, permanent increases in relative prices would be profitable.²⁸²

As in the US, it is common for EC authorities to define markets for pharmaceuticals very narrowly in abuse of dominance cases, sometimes using the market for one particular good as the relevant unit for analysis. In *Istituito Chemioterapico Italiano and Commercial Solvents Corporation* [1974] ECR. 223, the ECJ was faced with a complaint by a pharmaceutical product maker that it was denied the supply of an active ingredient needed to create the anti-tuberculosis drug ethambutol. The court affirmed the Commission's findings that the relevant market was the "separate market in the raw material for the manufacture of this product", in which the defendant was dominant, rather than the market for the end product itself.²⁸³ The court explained:

Contrary to the arguments of the applicants it is in fact possible to distinguish the market in raw material necessary for the manufacture of a product from the market on which the product is sold. An abuse of a dominant position on the market in raw materials may thus have effects restricting competition in the market on which the derivatives of the raw material are sold and these effects must be taken into account in considering the effects of an infringement, even if the market for the derivative does not constitute a self-contained market.

The Advocate General's opinion in the case argued that the Commission should define the relevant market as that for ethambutol itself, despite the presence of other anti-tubercular medicines, "because it was used in combination with other anti-tubercular drugs and was a complement of them rather than their competitor."²⁸⁴

In two recent cases, UK competition authorities have defined the relevant market for pharmaceuticals narrowly. In *Napp Pharmaceuticals*, the UK Director General of Fair Trading concluded that the relevant product market was sustained-release oral morphine, and should exclude immediate release, non-oral and non-morphine products. In each instance, the Director concluded that there was either no clinical substitution between the products outside the defined market or that the products outside the defined market did not constrain the pricing of sustained-release oral morphine.²⁸⁵

²⁸² European Commission, *Commission Notice On the Definition of the Relevant Market for the Purposes of Community Competition Law*, Section II, Published in the Official Journal: OJ C 372 on 9/12/1997. Available at http://europa.eu.int/comm/competition/antitrust/relevma_en.html. The Commission provides the following illustrative example:

A practical example of this test can be provided by its application to a merger of, for instance, soft drink bottlers. An issue to examine in such a case would be to decide whether different flavours of soft drinks belong to the same market. In practice, the question to address would be if consumers of flavour A would switch to other flavours when confronted with a permanent price increase of 5 percent to 10 percent for flavour A. If a sufficient number of consumers would switch to, say, flavour B, to such an extent that the price increase for flavour A would not be profitable due to the resulting loss of sales, then the market would comprise at least flavours A and B. The process would have to be extended in addition to other available flavours until a set of products is identified for which a price rise would not induce a sufficient substitution in demand

²⁸³ Para 19.

²⁸⁴ Opinion of Mr Advocate General Warner, quoted in Opinion of Mr Advocate General Jacobs delivered on 28 May 1998, *Oscar Bronner GmbH & Co. KG v Mediaprint*, [1998] ECR I-7791, para 60.

²⁸⁵ Decision of the Director General of Fair Trading, *Napp Pharmaceutical Holdings Limited and Subsidiaries (Napp)*, No. CA CA98/2/2001, 13-26 (30 March 2001) (concluding: "for the purposes of the present case, the

In Genzyme,²⁸⁶ the Director concluded that the relevant product market consisted only of Genzyme's product Cerezyme, a drug to treat Gaucher disease, and a single other product, Zavesca, a potential therapeutic substitute to treat Gaucher disease.²⁸⁷ As defined by the Commission, the given relevant market is extremely small since only about 180 people in the UK have Gaucher disease.²⁸⁸ The Director rejected arguments by Genzyme that the relevant market should include the broader class of products to treat all Lysosomal Storage Disorders, a category of 40 diseases including Fabry disease, Tay-Sachs disease, Sandhoff disease and Niemann-Pick disease.²⁸⁹

Broader definitions of the relevant market are prevalent in EC merger cases concerning pharmaceuticals. In these cases, the EC presumptively defines product markets based on the third level of the WHO's ATC system, which "provide a grouping of medicines according to their therapeutic indications, that is, their intended use".²⁹⁰ The Commission has noted that "[i]t may be necessary . . . to carry out analyses at other levels of ATC classification".²⁹¹ It has also stated that in some areas, any attempt to use ATC levels "may be problematical", drawing particular attention to "the HIV/AIDS area" as an example.²⁹²

3.2.2.2 Illegal Refusals to Deal in the European Community

Where dominance is shown, liability for a violation of the EC Treaty turns on whether the acts of firm have abused that position. The EC Treaty lists a number of specific acts that may constitute an illegal abuse of dominance, but a refusal to deal or refusal of access to an essential facility are not among them.²⁹³ EC case law, however, has held that a refusal to deal

immediate-release and the slow-release segments of the N2A ATC class will be considered to constitute two separate relevant markets." The Director General's decision was appealed and upheld. Competition Commission Appeal Tribunal, *Napp Pharmaceutical Holdings Limited and Subsidiaries and Director General of Fair Trading*, Case No. 1001/1/1/01 (15 January 2002).

²⁸⁶ Decision of the Director General of Fair Trading, *Exclusionary Behaviour by Genzyme Limited*, CA No. 93/3/03 (27 March 2003).

²⁸⁷ The Director argued there were strong reasons to exclude Zavesca from the relevant market, since it was only available to a limited pool of patients -- as a second-line treatment for those who could not tolerate Cerezyme -- but that inclusion of Zavesca did not affect the ultimate finding of dominance, and so it was therefore not necessary to reach a decision on the issue. Decision of the Director General of Fair Trading, *Exclusionary Behaviour by Genzyme Limited*, CA No. 93/3/03, 27 March 2003, 48-49.

²⁸⁸ Gaucher disease is a rarely occurring inherited disease that may include severe bone and liver impairments.

²⁸⁹ Decision of the Director General of Fair Trading, *Exclusionary Behaviour by Genzyme Limited*, CA No. 93/3/03, 27 March 2003, 51-52.

²⁹⁰ Commission of the European Communities, Article 6(1)(b) Non Opposition, Case No. IV/M.555 - *Glaxo/Wellcome*, paragraphs 6-9, 1995.

²⁹¹ *Id.* (noting that examples may include "where it is appropriate to group particular 3rd level categories together" because "products from different ATC classes compete as possible treatments for a specific diagnosed medical condition").

²⁹² Commission of the European Communities, Article 6(1)(b) Non Opposition, Case No. IV/M.555 - *Glaxo/Wellcome*, paragraphs 6-9, 1995; *see also* Commission of the European Communities, Article 6(1)(b) Non Opposition, Case No. IV/M.500, *American Home Products/American Cyanamid*, 1994 (stating that Commission's use of ATC3 is presumptive only and that the commission will consider a merger at ATC4 if supported by evidence).

²⁹³ The Treaty states that particular instances of abuse may include:

- (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;

by a dominant firm may violate EC competition law if (1) the refusal has a substantial anticompetitive effect or denies access to an essential facility and (2) there is no “objective justification” for the refusal.

EC case law on illegal refusals to deal is commonly described as beginning with the 1974 judgment of the ECJ in the case of *Istitutio Chemioterapico Italiano and Commercial Solvents Corporation* [1974] ECR. 223. In that case, the court held that a dominant supplier of a raw material needed to produce a tuberculosis treatment violated the act by refusing to supply a past customer seeking to produce the medicine. The court held that the refusal to deal had the substantial anticompetitive effect of preventing a potential competitor from supplying the local market and that the desire of the dominant firm to enter the market itself was not an adequate justification for refusing to supply the potential competitor:

[A]n undertaking being in a dominant position as regards the production of raw material and therefore able to control the supply to manufacturers of derivatives, cannot, just because it decides to start manufacturing these derivatives (in competition with its former customers) act in such a way as to eliminate their competition which in the case in question, would amount to eliminating one of the principal manufacturers of ethambutol in the common market. . . . [A]n undertaking which has a dominant position in the market in raw materials and which, with the object of reserving such raw material for manufacturing its own derivatives, refuses to supply a customer, which is itself a manufacturer of these derivatives, and therefore risks eliminating all competition on the part of this customer, is abusing its dominant position within the meaning of Article 86 [now article 82].²⁹⁴

The court considered a limited capacity to produce the material as being one possible justification for the refusal to deal, but rejected this justification as not being proven.²⁹⁵ Accordingly, the court ordered Commercial Solvents to supply the ingredients to the downstream manufacturer.²⁹⁶

In *United Brands and Commission of the EC* [1978] ECR. 207, the ECJ found that the distributor of Chiquita brand bananas abused its dominant position by cutting supplies to a Danish distributor that began advertising Dole brand bananas. The court described the anticompetitive effect of United Brands’ refusal to deal as including that “the refusal to sell would limit markets to the prejudice of consumers”. It also implied that United Brands intended to harm competition, stating that the firm

-
- (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 with the subject of such contracts.

Subsection (b) may be most applicable in refusal to deal cases that result in limited competition. *Cf. Glaxo v. Pharmaceutical Wholesalers*, South African Competition Court of Appeal (commenting that: “Neither article 82 of the EC Treaty, nor the Sherman Anti-Trust Act makes any express reference to the expression ‘essential facility’. What one finds are provisions relating to the general prohibition of abuse of a dominant position.”).

²⁹⁴ Para 25.

²⁹⁵ The court noted in para 28 that the parties “do not seriously dispute” that Commercial Solvents had the production capacity necessary to supply the applicant.

²⁹⁶ It was not discussed in the case whether the products at issue were patented by Commercial Solvents.

could not be unaware . . . that by acting in this way it would discourage its other ripener/distributors from supporting the advertising of other brand names and that the deterrent effect of the sanction imposed upon one of them would make its position of strength on the relevant market that much more effective.²⁹⁷

It agreed with the Commission that these anticompetitive effects “cannot be justified objectively”, and therefore the refusal to deal was illegal. The court specifically rejected the justification of United Brands that “in its own interest and that of competition” it had “no option but to fight back or else disappear from this national market.”²⁹⁸

3.2.2.3 Application of the Refusal to Deal Doctrine to Intellectual Property

In *Volvo v Erik Veng* [1988] ECR. 6211, the ECJ addressed “whether the refusal by the proprietor of a registered design . . . to grant a licence for the import and sale of such [protected products] may, in certain circumstances, be regarded as an abuse of a dominant position”. The court noted that, in normal circumstances, the refusal to licence a registered design should not be subject to liability as abusive conduct because the right of the proprietor of a protected design to exclude others from its use “constitutes the very subject-matter of his exclusive right.”

It follows that an obligation imposed upon the proprietor of a protected design to grant to third parties, even in return for a reasonable royalty, a licence for the supply of products incorporating the design would lead to the proprietor thereof being deprived of the substance of his exclusive right, and that a refusal to grant such a licence cannot in itself constitute an abuse of a dominant position.

The court continued, however, that this general rule may have exceptions. The court stated that “the exercise of an exclusive right by the proprietor of a registered design . . . may be prohibited by Article 86 if it involves, on the part of an undertaking holding a dominant position, certain abusive conduct” not present in the case.²⁹⁹

In *Radio Telefis Eireann v Commission of the EC* [1995] ECR. I-743 (referred to as *Magill*), the ECJ held that a special circumstance justifying compulsory licensing of an intellectual property right is where the refusal to licence prevents “the appearance of a new product . . . which the appellants did not offer and for which there was a potential consumer demand.”³⁰⁰ In that case, three television broadcasters held copyrights on their respective listings for broadcasts in Ireland. Each produced their own weekly listings, but refused to give permission for any firm to produce a comprehensive weekly guide. *Magill* challenged this policy as being an abuse of dominance that prevented it from publishing a comprehensive guide.

²⁹⁷ Para 192.

²⁹⁸ Para 177.

²⁹⁹ Para 9. In the context of the specific case, the court explained that such specific conduct might include “the arbitrary refusal to supply spare parts to independent repairers, the fixing of prices for spare parts at an unfair level or a decision no longer to produce spare parts for a particular model even though many cars of that model are still in circulation”.

³⁰⁰ Para 54.

In the initial proceedings, the EC Commission found that the anticompetitive effect of the refusal to licence included the denial of access to a combination product providing consumers all the needed listings for the week “in a reasonably practical way and without having to pay a considerable amount of money”.³⁰¹ The ECJ accepted these findings and added that there was “no actual or potential substitute for a weekly television guide offering information on the programmes for the week ahead”. It explained:

Thus the appellants – who were, by force of circumstance, the only sources of the basic information on programme scheduling which is the indispensable raw material for compiling a weekly television guide – gave viewers wishing to obtain information on the choice of programmes for the week ahead no choice but to buy the weekly guides for each station and draw from each of them the information they needed to make comparisons.

The appellants’ refusal to provide basic information by relying on national copyright provisions thus prevented the appearance of a new product, a comprehensive weekly guide to television programmes, which the appellants did not offer and for which there was a potential consumer demand.³⁰²

The court rejected the defendants’ arguments, which were based on the *Volvo* decision, that their intellectual property rights provided sufficient justification for the anticompetitive effect of their refusal to licence.

[T]he arguments of the appellants . . . wrongly presuppose that where the conduct of an undertaking in a dominant position consists of the exercise of a right classified by national law as ‘copyright’, such conduct can never be reviewed in relation to Article 86 of the Treaty.

Admittedly, . . . the exclusive right of reproduction forms part of the author’s rights, so that refusal to grant a licence, even if it is the act of an undertaking holding a dominant position, cannot in itself constitute abuse of a dominant position [citing *Volvo*].

However, it is also clear from that judgment (paragraph 9) that the exercise of an exclusive right by the proprietor may, in exceptional circumstances, involve abusive conduct.³⁰³

The court concluded that the prevention of a new product from reaching consumers was sufficient to meet the requirement that there be “exceptional circumstances”. “Such refusal constitutes an abuse under heading (b) of the second paragraph of Article 86 of the Treaty.”³⁰⁴

³⁰¹ *Magill TV Guide/ITP, BBC and RTE*, 89/205/EEC: Commission Decision of 21 December 1988, para 23.

³⁰² *Radio Telefis Eireann v Commission of the EC* [1995] ECR. I-743, paras 53-54.

³⁰³ *Id.* at paras 48-50.

³⁰⁴ Heading (b) defines an abuse of dominance as including: “limiting production, markets or technical development to the prejudice of consumers”.

3.2.2.4 The European Community Essential Facility Doctrine

The EC Commission first referred to a specific essential facilities doctrine in the interim order of *Sea Container v. Stena Sealink*.³⁰⁵ There, Sea Container sought to transport passengers and cars from Holyhead, Wales to Ireland, but Stena Sealink, which operated a similar service and owned the port facilities in Holyhead, refused to allow the competitor access. In holding that Sealink abused its dominant position under Article 86, the Commission described a specific essential facility doctrine emanating from prior cases including the Commission’s decision in *Magill* and the ECJ’s decision in *Commercial Solvents*:

An undertaking which occupies a dominant position in the provision of an essential facility and itself uses that facility (i.e. a facility or infrastructure, without access to which competitors cannot provide services to their customers), and which refuses other companies access to that facility without objective justification or grants access to competitors only on terms less favourable than those which it gives its own services, infringes Article 86 if the other conditions of that Article are met.³⁰⁶

The Commission considered the port of Holyhead an essential facility because of its geographic position. It found a denial of access to the facility because in the correspondence between the parties “Sealink did not conduct its negotiations . . . by proposing or seeking solutions to the problems it was raising” and it rejected all proposals “without making any counter offer or attempting to negotiate”. It found that this conduct “was not consistent with the obligations on an undertaking which enjoys a dominant position in relation to an essential facility.”³⁰⁷

The Court of First Instance was confronted with a claim of denial of access to an essential facility involving copyrighted material in *Tierce Ladbroke v. Commission of the EC* [1997] ECR. II-923. In that case, the largest horse-race betting establishment in Belgium alleged that a firm abused its dominance by refusing to licence copyrighted broadcasts of races. The court rejected the complaint because it did not find that the broadcasts were essential to the betting establishment.

The refusal to supply the applicant could not fall within the prohibition laid down by Article 86 [as described by *Magill*] unless it concerned a product or service which was either essential for the exercise of the activity in question, in that there was no real or potential substitute, or was a new product whose introduction might be prevented, despite specific, constant and regular potential demand on the part of consumers [citation to *Magill* omitted].

In this case . . . the televised broadcasting of horse races . . . is not in itself indispensable for the exercise of bookmakers’ main activity, namely the taking of bets Moreover, transmission is not indispensable, since it takes place after bets are

³⁰⁵ 94/19/EC: Commission Decision of 21 December 1993.

³⁰⁶ Para 66.

³⁰⁷ Para 70. The Commission did not analyze Sealink’s justifications for the denial of access, stating: “This question would be further examined in the context of any final decision in this case.” Para 76.

placed, with the result that its absence does not in itself affect the choices made by bettors and, accordingly, cannot prevent bookmakers from pursuing their business.³⁰⁸

A year later, in *Oscar Bronner v. Mediaprint* [1998] ECR. I-7791, the ECJ rejected a claim that a refusal of a dominant newspaper to grant a competitor access to its home-delivery scheme violated the essential facility doctrine. The Court explained that *Magill* held that a refusal to licence intellectual property may be an abuse “in exceptional circumstances,” which existed in that case because the licence was “indispensable for carrying on the business in question”, the refusal prevented “the appearance of a new product for which there was a potential consumer demand”, the refusal was “not justified by objective considerations” and it was “likely to exclude all competition in the secondary market”.³⁰⁹ It continued:

Therefore, even if that case-law on the exercise of an intellectual property right were applicable to the exercise of any property right whatever, it would still be necessary, for the *Magill* judgment to be effectively relied upon . . . , not only that the refusal of the service comprised in home delivery be likely to eliminate all competition in the daily newspaper market on the part of the person requesting the service and that such refusal be incapable of being objectively justified, but also that the service in itself be indispensable to carrying on that person’s business, inasmuch as there is no actual or potential substitute in existence for that home-delivery scheme.³¹⁰

The Court found that there were viable substitutes for the defendant’s facility because there exist “other methods of distributing daily newspapers” and “it does not appear that there are any technical, legal or even economic obstacles capable of making it impossible, or even unreasonably difficult, for any other publisher of daily newspapers to establish . . . its own nationwide home-delivery scheme and use it to distribute its own daily newspapers.”³¹¹

The Advocate General’s opinion in *Oscar Bronner* contains a fuller discussion of the development of the essential facilities doctrine in EC law.³¹² The AG noted that the ECJ had not yet referred to a specific essential facilities doctrine, but that such a doctrine could be described as motivating a number of prominent cases including *Commercial Solvents*, *United Brands*, and *Magill* and had been consistently applied by the Commission for some time.³¹³ According to the AG, the basic doctrine states:

a company which has a dominant position in the provision of facilities which are essential for the supply of goods or services on another market abuses its dominant position where, without objective justification, it refuses access to those facilities. Thus in certain cases a dominant undertaking must not merely refrain from anti-

³⁰⁸ Paras 131-132.

³⁰⁹ Para 40.

³¹⁰ Para 41.

³¹¹ Paras 43-44; *see also* para 46 (stating: “to be capable of being regarded as indispensable, it would be necessary at the very least to establish . . . that it is not economically viable to create a second home-delivery scheme”).

³¹² Opinion of Mr Advocate General Jacobs delivered on 28 May 1998, *Oscar Bronner GmbH & Co. KG v Mediaprint*, [1998] ECR I-7791.

³¹³ Paras 35-40, 48-53.

competitive action but must actively promote competition by allowing potential competitors access to the facilities which it has developed.³¹⁴

The AG observed that the Commission’s cases applying the doctrine paralleled US law in that refusal of access to an essential facility “can of itself be an abuse even in the absence of other factors, such as tying of sales, discrimination vis-a-vis another independent competitor, discontinuation of supplies to existing customers or deliberate action to damage a competitor”.³¹⁵ Citing *Magill*, the AG stated that “it also seems that an abuse may consist in mere refusal to licence where that prevents a new product from coming on a neighbouring market in competition with the dominant undertaking’s own product on that market.”³¹⁶ The AG also noted that an “essential facility can be a product such as a raw material or a service” and that an upstream/downstream market relationship was not required.³¹⁷

In assessing particular cases, the AG instructed that “it is important not to lose sight of the fact that the primary purpose of Article 86 is to prevent distortion of competition – and in particular to safeguard the interests of consumers”.³¹⁸ In intellectual property cases, he identified the key inquiry as involving “balancing of the interest in free competition with that of providing an incentive for R&D and for creativity.”³¹⁹ The AG noted the special circumstances present in *Magill* justifying that decision, including among them that the copyright in question “was difficult to justify in terms of rewarding or providing an incentive for creative effort.”³²⁰ He also noted that he might consider the degree of public funding of the facility in question as one factor weighing toward the grant of a compulsory licence.³²¹

In *European Night Services v. Commission of the EC*, [1998] ECR. II-3141, the Court of First Instance rejected a finding of the Commission that the locomotives and crews of a joint-venture supplying overnight rail services must be supplied to third parties on non-discriminatory terms. The decision turned primarily on the failure of the Commission to make proper findings on anticompetitive effects resulting from the joint venture. It added, however, that even assuming anticompetitive effects, the resources at issue were not “essential facilities” because locomotives and staff resources can be rented or purchased elsewhere.³²² The court explained that “a product or service cannot be considered necessary or essential unless there is no real or potential substitute”.³²³ This finding, in turn, cannot be supported “unless such infrastructure, products or services are not ‘interchangeable’ and

³¹⁴ Para 34.

³¹⁵ Para 50.

³¹⁶ Para 43.

³¹⁷ Para 50 (“In many cases the relationship is vertical in the sense that the dominant undertaking reserves the product or service to, or discriminates in favour of, its own downstream operation at the expense of competitors on the downstream market. It may however also be horizontal in the sense of tying sales of related but distinct products or services.”).

³¹⁸ Paras 56-58.

³¹⁹ Para 62 (noting that intellectual property laws that grant exclusivity for a limited time engage in this balancing and “[i]t is therefore with good reason that the Court has held that the refusal to license does not of itself, in the absence of other factors, constitute an abuse”).

³²⁰ Para 63. This factor has not been discussed by any court, but has been noted by other commentators. *See Korah*.

³²¹ Para 66 (“I do not rule out the possibility that the cost of duplicating a facility might alone constitute an insuperable barrier to entry. That might be so particularly in cases in which the creation of the facility took place under non-competitive conditions, for example, partly through public funding.”).

³²² Paras 212-18.

³²³ Para 208.

unless, by reason of their special characteristics – in particular the prohibitive cost of and/or time reasonably required for reproducing them – there are no viable alternatives available to potential competitors of the joint venture, which are thereby excluded from the market.”³²⁴

The most recent case to apply the essential facilities doctrine is the interim measures decision of the EC Commission in *NDC Health and IMS Health* Comp D3/38.044 (3 July 2001), which were recently withdrawn in a decision that does not affect the reasoning of the decision.³²⁵ In that case, the Commission ordered IMS to grant a licence to its copyrighted “1860 brick structure”, which is a data analysis tool used by pharmaceutical companies to analyse sales information in Germany. The complainant was a competitor that wished to compete in the market for providing the data to pharmaceutical companies.

Citing *Bronner*, the Commission stated that abuse of dominance in cases relating to the exercise of a property right, including intellectual property, can be established where:

- the refusal of access to the facility is likely to eliminate all competition in the relevant market;
- such refusal is not capable of being objectively justified; and
- the facility itself is indispensable to carrying on business, inasmuch as there is no actual or potential substitute in existence for that facility.³²⁶

The Commission determined that “exceptional circumstances” existed in which “a refusal to grant a licence may constitute abusive conduct in itself” under *Magill*.³²⁷ Following an essential facility analysis, the Commission found that the copyrighted system was “indispensable to compete” with IMS. This was because IMS developed the copyrighted structure in conjunction with the pharmaceutical companies, which adopted it as “a de facto industry standard.”³²⁸ It would be “unreasonably difficult for other undertakings to create another structure in which regional data services could be formatted and marketed in Germany” because of both “technical and legal restraints”.³²⁹

In the second inquiry, the Commission rejected IMS’s proffered justifications. It held that NDC’s challenge to the validity of the copyright in German courts did not justify the refusal to licence because the licence “would not . . . impact on the question under German law of whether a copyright exists or not, and if so, who owns it”. It also found that IMS had not substantiated its allegation that the royalty offered by NDC was insufficient because it failed

³²⁴ Para 209.

³²⁵ Dow Jones Business News, *EU Commission Withdraws Order Against IMS Health* (13 August 2003) (quoting the Commission’s statement that the order was withdrawn because litigation in Germany had solved the underlying copyright dispute and therefore “There is no longer an urgency requiring the Commission’s intervention”); cf. Frank Fine, *NDC/IMS: A Logical Application of the Essential Facilities Doctrine* (discussing the case and opinion of the Dutch antitrust authorities that the Commission decision in the NDC case “is entirely consistent with the applicable EC precedents”).

³²⁶ Para 70.

³²⁷ Para 168.

³²⁸ Para 123.

³²⁹ Paras 124-152. The legal restraints included German privacy laws that restricted the information that could be collected and “legal uncertainty” that any new structure may have in relation to IMS’s copyright.

to make “any counter proposal or suggest[] an amount that it considered reasonable.”³³⁰ Finally, criminal allegations of theft of property by IMS against NDC did not justify a refusal because IMS should “address any perceived harm [from] alleged criminal behaviour through appropriate lawful means, and not by attempting to eliminate competition in the relevant market”.³³¹

In *Intel v. Via Technologies* [2003] F.S.R. 33, the U.K. Court of Appeal rejected an argument that the ECJ. jurisprudence thus far has produced a closed list of the “exceptional circumstances” that may justify a compulsory licence under EC competition law. In that case, the court considered whether a refusal to licence in violation of EC law could be used as a defence to a patent infringement action brought by Intel. The court held that the issue could not be decided on summary motions before trial. In so holding, the court rejected Intel’s arguments that, under *Magill*, *Bronner*, and *IMS*, the only “exceptional circumstances” justifying a finding of abuse of dominance by a refusal to licence is “if all the conditions in either *Magill* or *IMS* are satisfied”, that is: “the result of the refusal must be to exclude an entirely new product from the market (*Magill*) or all competition to the patentee (*IMS*).”³³² The court held:

It does not follow [from *Magill* and *IMS*] that other circumstances in other cases will not be regarded as exceptional. In particular it is at least arguable, as the President recognised in *IMS*, that the Court of Justice will assimilate its jurisprudence under Art.82 more closely with that of the essential facilities doctrine applied in the United States. In that event there could be a breach of Art.82 without the exclusion of a wholly new product or all competition. This approach seems to me to be warranted by the width of the descriptions of abuse contained in Art.82 itself.

I would, in any event, reject the submission of counsel for Intel that the IMS test requires the exclusion of all competition from all sources. This was not a requirement in Oscar Bronner which referred . . . only to all competition from the person requesting the service. . . . Were it otherwise liability under Art.82 could be simply avoided by the grant of a licence to an unenergetic rival.³³³

3.2.3 Canada

Canada has long imposed obligations to licence patents through its patent and competition laws.³³⁴ These obligations have historically been far more aggressive than the standards in the US and EC and therefore have frequently been cited as models for developing countries by academics as well as the United Nations Development Programme.³³⁵

³³⁰ Para 172.

³³¹ Para 173.

³³² Para 47.

³³³ Para 48-49.

³³⁴ See Jerome Reichman and Catherine Hasenzahl, *Non-voluntary Licensing of Patented Inventions: The Canadian Experience*, UNCTAD/ICTSD Capacity Building Project on Intellectual Property and Sustainable Development (October 2002) (hereinafter “*The Canadian Experience*”).

³³⁵ See UNDP, Human Development Report (2001); Jerome Reichman Expert Report; *The Canadian Experience*.

3.2.3.1 Compulsory Licensing Scheme for Medicines

In 1923, Canada first introduced into its patent legislation special provisions authorising the compulsory licensing of patented pharmaceutical and food products, but the provisions were rarely used.³³⁶ In 1963, the Restrictive Trade Practices Commission (RTPC) issued its Report Concerning the Manufacture, Distribution and Sale of Drugs, which found that the prices of patented medicines in Canada “were excessive; that there was little price competition; and that patents inhibited competition.”³³⁷ It further stated that “the control over drugs exercised through patents in Canada was disadvantageous to Canadian consumers because it enabled the drug suppliers to charge high prices in relation to their cost, production and distribution.”³³⁸ In 1964, the Royal Commission on Health Services (referred to as the “Hall Commission”) declared that “either the industry will make . . . drugs available at the lowest possible cost, or it will be necessary for . . . government to do so.”³³⁹

In 1969, the Canadian Parliament amended the Patent Act to increase the use of compulsory licences for medicines. Section 41(4) of the 1969 Act created a presumption in favour of granting compulsory licences for pharmaceutical products, stating: “the Commissioner shall grant to the applicant a licence to do the things specified in the application except such, if any, of those things in respect of which he sees good reason not to grant such a licence”.³⁴⁰ It further stated that “in settling the terms of the licence and fixing the amount of royalty or other consideration payable, the Commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be prescribed.”³⁴¹

³³⁶ *The Canadian Experience* at 33.

³³⁷ *The Canadian Experience* at 33 (quoting Restrictive Trade Practices Commission, *Report Concerning the Manufacture, Distribution and Sale of Drugs* (1963)).

³³⁸ *The Canadian Experience* at 26.

³³⁹ *The Canadian Experience* at 33 (quoting Royal Commission on Health Services, *Report* 40 (1964)).

³⁴⁰ Section 41(4) of the 1969 Act provided:

Where, in the case of any patent for an invention intended or capable of being used for medicine or for the preparation or production of medicine, an application is made by any person for a license to do one or more of the following things as specified in the application, namely:

- (a) where the invention is a process, to use the invention for the preparation or production of medicine, import any medicine in the preparation or production of which the invention has been used or sell any medicine in the preparation or production of which the invention has been used, or
- (b) where the invention is other than a process, to import, make, use or sell the invention for medicine or for the preparation or production of medicine, the Commissioner shall grant to the applicant a licence to do the things specified in the application except such, if any, of those things in respect of which he sees good reason not to grant such a licence; and, in settling the terms of the licence and fixing the amount of royalty or other consideration payable, the Commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be prescribed.

³⁴¹ See *The Canadian Experience* at 35 (“Although the Commissioner, in his discretion, could deny an application for cause, he rarely did so. Short of a showing that the applicant was bankrupt or had submitted false statements, the Commissioner tended to reject all other objections. It was reportedly his view that ‘the grant of a compulsory license would lead to enhanced competition and . . . this would lead to lower prices for pharmaceutical products,’ which was the underlying statutory objective”) (citations omitted).

Between 1969 and 1992, 613 licences for patented medicines were granted under the special compulsory licence scheme in the Patent Act. Under the requirement that the patentee receive “due reward for the research leading to the invention and for such other factors as may be prescribed”, the Commissioner established, and courts approved, a “rule of thumb” granting a royalty of four percent of the net selling price of the drug by the licensee, and this formula was routinely applied until courts began to shift the royalty payment higher just before the programme was abolished in 1992.³⁴²

In 1985, the Royal Commission of Inquiry on the Pharmaceutical Industry (referred to as the “Eastman Commission”) delivered a report concluding that the compulsory licensing scheme had not adversely affected the research-based Canadian pharmaceutical industry or the R&D decisions of the multinational pharmaceutical industry and that the program had saved Canadian consumers \$200 million in 1983 alone.³⁴³

3.2.2.2 Post-1992 Abuse Standards

The Patent Act Amendment Act of 1992, which took effect on March 12, 1993, abolished the special scheme for compulsory licences for patented medicines.³⁴⁴ Current Canadian law retains, however, authorisation of compulsory licences for failure to meet demand for the patented article to an adequate extent and on reasonable terms. Although this ground has not been frequently used, commentators have noted that “this ground of abuse could apply to future cases in which a foreign pharmaceutical producer did fail to supply the Canadian market with needed medicines at affordable prices”; “pricing the product too far beyond the reach of consumers willing to buy it - i.e., creating unacceptable dead weight loss - can be treated as an abusive failure to satisfy demand within the ambit of this provision.”³⁴⁵

Current Canada law also authorises compulsory licences when the patent holder refuses either to licence at all, or to licence on reasonable terms, provided that such conduct prejudices “the trade and industry of Canada, or the trade of any person or class of persons trading in Canada, or the establishment of any new trade or industry in Canada” and the issuance of the compulsory licence will serve the public interest.³⁴⁶ Case law suggests that “reasonable terms” primarily refers to a “reasonable price in money”.³⁴⁷

³⁴² *The Canadian Experience* at 37-38 (noting that in 1991 the Federal Court of Appeal suggested that an automatic royalty rate was legally insufficient and higher royalty rates were subsequently applied in two 1992 cases before the scheme was abolished in 1993).

³⁴³ *The Canadian Experience* at 38. The report suggested granting only four years of exclusive patent protection for pharmaceutical products (without compulsory licensing in those years) following which compulsory licensing would proceed as of right at a higher royalty rate than the traditional four percent for companies that engaged in R&D in Canada.

³⁴⁴ *The Canadian Experience* at 43. Prior to this change, a set of amendments in 1987 granted patent holders a seven year period of exclusivity in which compulsory licences would not be granted and established a Patent Medicine Prices Review Board with authority to punish patent holders that sold pharmaceutical products at excessive prices. Reichman and Hasenzahl note that “[t]here is no consensus . . . that Canada benefited from increased foreign investment in the pharmaceutical sector during this period or even that the PMPRB succeeded in controlling the rise of drug prices.” *The Canadian Experience* at 41-42.

³⁴⁵ *The Canadian Experience* at 22; see also Paul Torremans, *Compulsory Licensing of Pharmaceutical Products in Canada*, 27 Int’l Rev. Indus. Prop. & Copyright Law 316, 326-27 (1996).

³⁴⁶ Patent Act, R.S.C. 1985, c.P-4, §65(2)(d).

³⁴⁷ *The Canadian Experience* at 23 (citing authorities).

3.2.2.3 Canada's Competition Act

Section 32 of the Canadian Competition Act authorises the Attorney General of Canada to apply to the Federal Court for an order to prevent use of intellectual property that “unduly” prevents or lessens competition.³⁴⁸ Remedies available to the Federal Court include directing the grant of licences on such terms as it deems appropriate or revoking the patent.³⁴⁹

Section 79 defines the general Canadian abuse of dominance standard, but excludes acts pursuant only to the exercise of any right or enjoyment of any interest derived under intellectual property statutes. Commentators have pointed out that: “The wording of [the exemption] indicates clearly that the provisions remain applicable to practices that are shown to constitute abuses of intellectual property rights, as opposed to the mere exercise of such rights.”³⁵⁰

There are few known uses of the Canadian Competition Act in cases involving abuse of pharmaceutical patents. In 1965, however, the RTPC issued a report that exclusive patent and trademark rights had been abused by a chemical supplier when the proprietor refused to sell a plant growth chemical to one of its former distributors. The report stated: “where a

³⁴⁸ The full section reads:

32. (1) In any case where use has been made of the exclusive rights and privileges conferred by one or more patents for invention, by one or more trade-marks, by a copyright or by a registered integrated circuit topography, so as to

- (a) limit unduly the facilities for transporting, producing, manufacturing, supplying, storing or dealing in any article or commodity that may be a subject of trade or commerce,
- (b) restrain or injure, unduly, trade or commerce in relation to any such article or commodity,
- (c) prevent, limit or lessen, unduly, the manufacture or production of any such article or commodity or unreasonably enhance the price thereof, or
- (d) prevent or lessen, unduly, competition in the production, manufacture, purchase, barter, sale, transportation or supply of any such article or commodity,

the Federal Court may make one or more of the orders referred to in subsection (2) in the circumstances described in that subsection.

³⁴⁹ Section 32(2) states:

The Federal Court, on an information exhibited by the Attorney General of Canada, may, for the purpose of preventing any use in the manner defined in subsection (1) of the exclusive rights and privileges conferred by any patents for invention, trade-marks, copyrights or registered integrated circuit topographies relating to or affecting the manufacture, use or sale of any article or commodity that may be a subject of trade or commerce, make one or more of the following orders:

- (a) declaring void, in whole or in part, any agreement, arrangement or licence relating to that use;
- (b) restraining any person from carrying out or exercising any or all of the terms or provisions of the agreement, arrangement or licence;
- (c) directing the grant of licences under any such patent, copyright or registered integrated circuit topography to such persons and on such terms and conditions as the court may deem proper or, if the grant and other remedies under this section would appear insufficient to prevent that use, revoking the patent;
- (d) directing that the registration of a trade-mark in the register of trade-marks or the registration of an integrated circuit topography in the register of topographies be expunged or amended; and
- (e) directing that such other acts be done or omitted as the Court may deem necessary to prevent any such use.

³⁵⁰ *The Canadian Experience at 32; see also* Competition Law of Canada (Davies, Ward and Beck, eds. 1999) (stating the need for courts to “draw the line between the mere exercise of statutory rights and the misuse of an intellectual property right”).

manufacturer enjoys a sole position in a market, that power must not be used to limit distribution for the purpose of controlling competition in the marketplace.” Ultimately, however, no action was taken in this due to a subsequent collapse in the market for the product in question.³⁵¹

The Canadian Competition Bureau’s Intellectual Property Enforcement Guidelines (2000) are similar to the US FTC/DOJ guidelines in that they 1) generally equate the treatment of intellectual property with that of other forms of property;³⁵² 2) do not equate the exercise of exclusive rights with market power in the absence of evidence about the extent to which effective substitutes constrain the intellectual property owner’s pricing,³⁵³ and 3) presume that the licensing of intellectual property rights is pro-competitive.³⁵⁴

The Guidelines state that “[t]he analytical framework that the Bureau uses to determine the presence of anti-competitive effects stemming from the exercise of rights to other forms of property is sufficiently flexible to apply to conduct involving IP, even though IP has important characteristics that distinguish it from other forms of property.”³⁵⁵ This framework generally balances the costs and benefits of a specific action to consumer interests.³⁵⁶

In cases involving intellectual property under section 32, the Bureau’s position is that the Federal Court must “balance the interests of the system of protection for IP (and the

³⁵¹ *The Canadian Experience* at 28.

³⁵² Canadian Competition Bureau, *Intellectual Property Enforcement Guidelines* at 6 (describing the Bureau’s approach with intellectual property cases as “consistent with its approach to all forms of property”); *id* at 1 (“Owners of IP, like owners of any other type of private property, profit from property laws that define and protect owners’ rights to exclude others from using their private property”).

³⁵³ Canadian Competition Bureau, *Intellectual Property Enforcement Guidelines* at 6 (explaining that “the right to exclude others from using the product does not necessarily grant the owner market power. . . . The existence of a variety of effective substitutes for the IP and/or a high probability of entry by other players into the market (by “innovating around” or “leap-frogging over” any apparently entrenched position) would likely cause the Bureau to conclude that the IP has not conferred market power on its owner.”).

³⁵⁴ Canadian Competition Bureau, *Intellectual Property Enforcement Guidelines* at 6 (“In the vast majority of cases, licensing is pro-competitive because it facilitates the broader use of a valuable IP right by additional parties.”).

³⁵⁵ Canadian Competition Bureau, *Intellectual Property Enforcement Guidelines* at 2. The Guidelines explain: Private property rights are the foundation of a market economy. Property owners must be allowed to profit from the creation and use of their property by claiming the rewards flowing from it. In a market system this is accomplished by granting owners the right to exclude others from using their property, and forcing those wishing to use it to negotiate or bargain in the marketplace for it, thereby rewarding the owner. This creates incentives to invest in developing, and leads to the exchange of, private property, thus contributing to the efficient operation of markets.

...

IP has unique characteristics that make it difficult for owners to physically restrict access to it and, therefore, exercise their rights over it. The owner of physical property can protect against its unauthorized use by taking appropriate security measures, such as locking it away, but it is difficult, if not impossible, for the creator of a work of art to prevent his or her property from being copied once it has been shown or distributed. This is exacerbated because IP, while often expensive to develop, is often easy and inexpensive to copy. IP is also typically non-rivalrous — that is, two or more people can simultaneously use IP. The fact that a firm is using a novel production process does not prevent another firm from simultaneously using the same process. In contrast, the use of a physical property by one firm prevents concurrent use by another.

³⁵⁶ Canadian Competition Bureau, *Intellectual Property Enforcement Guidelines* at 3 (“Competition law seeks to prevent companies from inappropriately creating, enhancing or maintaining market power that undermines competition without offering offsetting economic benefits.”).

incentives created by it) against the public interest in greater competition in the particular market under consideration.”³⁵⁷ In performing this balance in individual investigations, the Bureau uses two steps:

In the first step, the Bureau establishes that the mere refusal (typically the refusal to licence IP) has adversely affected competition to a degree that would be considered substantial in a relevant market that is different or significantly larger than the subject matter of the IP or the products or services which result directly from the exercise of the IP. This step is satisfied only by the combination of the following factors:

- i) the holder of the IP is dominant in the relevant market; and,
- ii) the IP is an essential input or resource for firms participating in the relevant market — that is, the refusal to allow others to use the IP prevents other firms from effectively competing in the relevant market.

In the second step, the Bureau establishes that invoking a special remedy against the IP right holder would not adversely alter the incentives to invest in research and development in the economy. This step is satisfied if the refusal to licence the IP is stifling further innovation.³⁵⁸

It does not appear that the Bureau has sought to enforce the Competition Act with regard to a refusal of a patent holder to grant a licence on reasonable terms since these guidelines were drafted.

3.3 SOUTH AFRICAN PRECEDENT

As under the competition laws of the countries reviewed above, analysis under the South African Competition Act follows a basic two step inquiry. First, it must be determined whether the respondent is dominant in the relevant market. Next, the firm’s conduct is assessed under the particular abuse provisions in the Act.

Unlike the countries reviewed above, South Africa has a specific statutory doctrine regarding the denial of essential facilities (section 8(b)). The Act does not, however, have an explicit provision governing refusals to deal with competitors, other than refusals to supply “scarce goods”. Refusals to licence intellectual property therefore appear most directly addressed under the essential facilities doctrine as well as under the broader prohibition of “exclusionary acts” the anticompetitive effect of which outweigh offsetting procompetitive benefits (section 8(c)).

³⁵⁷ Canadian Competition Bureau, *Intellectual Property Enforcement Guidelines* at 9.

³⁵⁸ Canadian Competition Bureau, *Intellectual Property Enforcement Guidelines* at 9. (“If factors i) and ii) are present then the IP is the source of dominance in a relevant market and other competitors would be able to participate in the relevant market only by having access to that IP. If the refusal is stifling further innovation then the Bureau would conclude that incentives to invest in R&D have been harmed by the refusal and a special remedy would help realign these incentives with the public interest in greater competition.”).

3.3.1 Dominance in the Relevant Market

The first step in analysis under the South African Competition Act is to determine whether the respondent is dominant in the relevant market. Under the Act, a firm is dominant in a market if --

- (a) it has at least 45 % of that market;
- (b) it has at least 35%, but less than 45% of that market, unless it can show that it does not have market power; or
- (c) it has less than 35 percent of that market, but has market power.³⁵⁹

Under the Act, “‘market power’ means the power of a firm to control prices, or to exclude competition or to behave to an appreciable extent independent of its competitors, customers or suppliers.”³⁶⁰

In defining relevant markets in abuse of dominance cases, the Competition Tribunal has proceeded on a case-by-case basis, examining the facts of particular cases, and generally favouring narrow product markets. The Tribunal has held, for example, that the relevant market is city-to-city airline routes, rather than the national market,³⁶¹ and sports drinks, rather than non-alcoholic beverages.³⁶²

Like all markets, that for pharmaceuticals evidences special features. The Competition Tribunal has held that because all pharmaceuticals are not substitutable in a therapeutic sense and do not compete against each other in an economic sense, “there can be no aggregation of pharmaceutical products into a single pharmaceutical market.”³⁶³

In two pharmaceutical cases,³⁶⁴ the Competition Tribunal has looked to therapeutic classes to define markets, and defined the relevant market as co-extensive with ATC3 categories.³⁶⁵ In *National Association of Pharmaceutical Wholesalers and Glaxo Wellcome*, the Competition Tribunal stated:

Given that a pharmaceutical product intended for one therapeutic use cannot be substituted by a product intended for another therapeutic use, anti-trust investigations of the pharmaceutical industry tend to use the ATC3 categories as the bases for

³⁵⁹ Competition Act, Chapter 2, Section 7.

³⁶⁰ Competition Act, Chapter 1, Section 1.1 (xiv).

³⁶¹ *Nationwide Airlines and South African Airways Limited*, Republic of South Africa, Case no. 92/IR/Oct00, (Competition Tribunal), 6-7.

³⁶² *Bromor Foods and National Brands*, Case No: 19/LM/Feb00 (Competition Tribunal), Paragraph 8-15.

³⁶³ *National Association of Pharmaceutical Wholesalers and Glaxo Wellcome*, Case No: 68/IR/JUN 00 (Competition Tribunal).

³⁶⁴ *National Association of Pharmaceutical Wholesalers and Glaxo Wellcome*, Case No: 68/IR/JUN 00 (Competition Tribunal); and *In the matter between Glaxo Wellcome SmithKline Beecham and The Competition Commission*, Case Number: 58/AM/May00 (Competition Tribunal), paragraph 11.

³⁶⁵ There are two ATC systems to classify pharmaceuticals. They are similar but not identical. One is maintained by the European Pharmaceutical Marketing Research Association (EphMRA), available at www.ephmra.org/atc/6_000.html. A separate ATC system is maintained by the WHO, available at www.whooc.no/atcddd/indexdatabase. The third level of each ATC system groups drugs into therapeutic classes, the fourth level places them into subtherapeutic groups. The EphMRA system does not contain a fifth level; for the WHO system, the fifth level is the chemical substance.

identifying the relevant pharmaceutical product markets. While we are alert to the possibility that an uncritical adoption of the ATC3 categories may occasionally produce somewhat distorted outcomes from an anti-trust perspective, for the purposes of interim relief the therapeutic categories are an acceptable proxy for identifying relevant markets.³⁶⁶

Glaxo involved a marketing arrangement put in place by pharmaceutical manufacturers and affected a broad swath of the pharmaceutical industry. As the Tribunal noted, the decision to rely on ATC3 categories in this instance had the effect of substantially narrowing the market from the potential alternative of considering the entire industry as the market. The Tribunal noted, however, that the use of the ATC3 classification will not be appropriate for every case:

Using the ATC categories as the basis for determining the boundaries of the relevant market may lead to overly narrow markets because in certain instances it may be possible to substitute from outside of a given ATC designation. In other instances, the market definition derived from the ATC categories may be too broad insofar as particular consumers may not be able to substitute across the full range within an ATC category.³⁶⁷

These decisions appear to be consistent with the precedents from other countries discussed above, and do not preclude South African competition authorities from defining markets much more narrowly in particular cases, including as the markets for particular formulations of a specific medicine as is frequently the case in US and EC analysis.

3.3.2 Applicability of Section 8 to Intellectual Property

It is clear from the text of the Competition Act that its prohibitions were intended to extend to the actions of intellectual property owners; i.e. that intellectual property rights do not provide an exemption to or otherwise immunise the holder from competition law violations. Section 10 provides:

A firm may apply to the Competition Commission to exempt from the application of this Chapter 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 . . . the Patents Act, 1978 (Act No. 57 of 1978)

There would, of course, be no need for an exemption for intellectual property if the Act itself did not apply to the actions of firms protected by Intellectual Property laws. It is also notable that the grant of an exemption is not mandatory. “Upon receiving an application in terms of subsection (4), the Competition Commission *may* grant an exemption for a specified term” (emphasis added).

³⁶⁶ *National Association of Pharmaceutical Wholesalers and Glaxo Wellcome*, Case No: 68/IR/JUN 00 (Competition Tribunal) (citation omitted).

³⁶⁷ *National Association of Pharmaceutical Wholesalers and Glaxo Wellcome*, Case No: 68/IR/JUN 00 (Competition Tribunal), fn 11.

3.3.3 Section 8(b): The Essential Facility Doctrine

Section 8(b) of the Competition Act states that it is prohibited for a dominant firm to “refuse to give a competitor access to an essential facility when it is economically feasible to do so”. In the definitions section, an essential facility is defined as “an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers”.³⁶⁸

As described by the Competition Appeal Court in *Glaxo v. National Association of Pharmaceutical Wholesalers*,³⁶⁹ the essential facilities doctrine in 8(b) and the prohibitions of certain “exclusionary acts” in section 8(c) and (d) differ. 8(b) defines a *per se* prohibition, which “allow[s] for no justification” other than the lack of economic feasibility. Under sections 8(c) and (d), “firms accused of engaging in exclusionary acts may raise the defence that the technological efficiency or other pro-competitive gains which flow outweigh its anticompetitive effect.”³⁷⁰

The court in *Glaxo* specifically distinguished an essential facility case under 8(b) from a section 8(d)(ii) case alleging a refusal of a dominant firm to supply “scarce goods”. The court held that a complaint alleging that Glaxo ceased wholesale discounts to distributors of its products was not properly brought under the essential facilities doctrine because the complaint involved the terms on which goods would be provided to the distributors, not the restriction of “an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services”. The court reasoned that “‘resource’ was not meant to be interpreted as products, goods or services. I cannot agree with the complainants that pharmaceutical products qualify as essential facilities and resources for anti-trust purposes.”³⁷¹

Under the reasoning in *Glaxo*, it appears that access to intellectual property through a licence would be considered a resource necessary to produce a good (i.e. medicine) under section 8(b), since such access is not a request for the good itself.³⁷² This view is in accord with the Competition Commission’s publicly released interpretations of the Act, which note that “potential examples of essential facilities include infrastructure and other assets that are too costly or environmentally undesirable to duplicate . . . and, in some cases, intellectual property rights.”³⁷³ Because the Competition Appeal Court has held that a “resource” under section 8(b) “was not meant to be interpreted as products, goods or services” under section 8(d)(ii), requests for licences of intellectual property to produce competing goods do not appear properly raised under section 8(d)(ii).

Although the Appeal Court did not apply the essential facility doctrine in *Glaxo*, it did outline what it considered to be the basic elements of a case under section 8(b). The court defined the basic elements of an essential facility claim as being:

³⁶⁸ Section 1(viii).

³⁶⁹ Case No: 15/CAC/Feb02.

³⁷⁰ Para 51.

³⁷¹ Para 53.

³⁷² See Carlos Correa Expert Report.

³⁷³ http://www.compcom.co.za/resources/brochure2/pages/04_dominant.htm.

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.³⁷⁴

Most of these elements are in accord with the cases from other countries describing the essential facilities doctrine in their laws. The statement that “the complainant and the dominant firm are competitors” appears tailored to the facts of that case. Section 8(d) prohibits a dominant firm from giving “a competitor access” to an essential facility, and therefore the complainant in the case will often be a competitor. In many cases, however, it may be a customer or public interest organisation that seeks to bring a case and nothing in the act clearly precludes such action. Indeed, the Competition Commission is authorised to be a complainant, although it will never be a competitor with the respondent. Accordingly, the statement in *Glaxo* that the complainant will be a competitor may be best interpreted as a general rule of thumb rather than a requirement in the statute.

3.3.4 Section 8(c): Exclusionary Act

Section 8(c) states that it is prohibited for a dominant firm to “engage in an exclusionary act... if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain”. The definitions section defines an exclusionary act as “an act that impedes or prevents a firm entering into, or expanding within, a market”.³⁷⁵

The two major cases to consider exclusionary act claims have turned on whether the complained-of acts impeded a firm from entering or expanding within a market. In *York Timbers Limited and South African Forestry Company Limited*,³⁷⁶ the Competition Tribunal was confronted with an allegation that a supplier of raw timber had violated sections 8(c) and (d)(ii) by reducing its supply to a downstream sawmill. The Tribunal found no refusal of supply because York was left free to submit tenders on remaining supplies on equal terms and had recently won a tender. Assuming a refusal to supply, the Tribunal examined the doctrine as explained by Areeda and Hovenkamp:

An ‘arbitrary’ refusal to deal by a monopolist cannot be unlawful unless it extends, preserves, creates, or threatens to create significant market power in some market,

³⁷⁴ Para 57.

³⁷⁵ Section 1(x).

³⁷⁶ Case Number: 15/IR/Feb01.

which could be either the primary market in which the monopoly firm sells or a vertically related or even collateral market.³⁷⁷

The Tribunal found that an illegal refusal to deal did not occur in the case because there was no information in the case “that suggests that an attack by SAFCOL on York would, even if successful, create new sources of market power for SAFCOL.”³⁷⁸ For the same reasons, it dismissed the 8(c) claim.³⁷⁹

In *Msoni v. British American Tobacco*,³⁸⁰ the Tribunal rejected a challenge by distributors to a change in British American Tobacco’s compensation system that negatively affected tobacco-only retailers. The tribunal explained:

In order to succeed with this allegation the applicants need to show that the new agreement will be exclusionary in that it either excludes competitors of the respondent from the market or the applicants themselves.³⁸¹

The applicants argued that the reduction of their margins and the increased costs of complying with the new system would prevent them from expanding in the cigarette distribution market and, similarly, that these requirements would prevent new entry into the market. The Tribunal rejected both claims, explaining that section 8(c) “cannot mean that every harshly imposed commercial term by a dominant firm constitutes an exclusionary act because it makes life more difficult for the firm imposed upon.”³⁸²

3.4 CONCLUSION

Constitutional and international human rights obligations require South African administrative and judicial authorities to interpret legislation in a manner that promotes the right of all South Africans to health care services, including access to needed medicines.

³⁷⁷ *York* at para 93. Similarly, Pitofsky et al comment that “there is no requirement that a plaintiff alleging anticompetitive denial of access to an essential facility demonstrate the existence of two separate relevant product markets.”

It is sufficient to prove that the parties compete or would compete if the plaintiff were permitted access to the defendant’s asset in the same ultimate market. . . . The courts require only that the plaintiff prove that the facility is indispensable for competition in a relevant product market, is controlled by a monopolist who could practically make access available, and is not capable of duplication.

³⁷⁸ Para 98.

³⁷⁹ The Tribunal explained at para 100:

This section places a considerably heavier burden on the applicant than does Section 8(d). As already elaborated, we are not persuaded that the practice complained of, the reduction in the guaranteed supply from Witklip, is ‘exclusionary’ within the meaning of the Act – that is, it does not impede or prevent the applicant from expanding in the market but merely requires that it competes for its supply of raw material on terms similar to those available to its competitors. Moreover, even if the practice complained of were to be established as an impediment to the applicant’s expansion in the market, it still remains for the applicant to establish the ‘anti-competitive effect’ of the practice, to show, in other words, that market power has been created or extended in consequence of the alleged act. This has not been done. And, even if anti-competitive effects had been established, the applicant would have to show that these outweighed any pro-competitive gains – this, too, has not been established.

³⁸⁰ Case No: 49/1R/Jul02.

³⁸¹ Para 57.

³⁸² Para 59 (quoting *York*: “It is not enough to show that a given practice is a product of market power. It must also be shown that the act complained of actually extends that power or creates new sites of power.”).

Human rights and public health obligations to promote access to medicines through interpretation of international and local law are explicitly recognised in the WTO's TRIPS Agreement, an authoritative interpretation of which encourages states to promote "access to medicines for all" through the flexibilities in the agreement.

South African and comparative law from the US, EC and Canada demonstrate that there is a wide range of acceptable approaches for applying competition regulations to intellectual property owners. These approaches range from standards that grant intellectual property owners immunity from obligations to licence others (in a limited number of US cases) to standards that create heavy presumptions in favour of licensing all pharmaceutical patents (Canada from 1923-1992).

When cases involving access to needed medicines are at issue, it appears that standards closer to that of Canada until the early 1990s, and further from the kind of blanket immunity for use of intellectual property that appears to be favoured by the Federal Circuit in the US, will best meet South Africa's constitutional and human rights obligations, while respecting its international obligations under TRIPS.

SECTION 4: PROPOSED INTERPRETATIONS

Based on the foregoing, this section proposes interpretations of the Competition Act for cases involving intellectual property that are tailored to meeting human rights and constitutional obligations.

4.1 DOMINANCE

4.1.1.1 Proposed Interpretation

A patent which enables a manufacturer to set price for a product confers market power. Patents that block effective generic competition for pharmaceuticals, including patents on active ingredients, for a particular product presumptively create market power.

4.1.1.2 Commentary

Assessing dominance in the presence of intellectual property rights may call for special considerations. The proposed interpretation follows the prevailing international approach in not presuming that patents, in general, confer market power. It adopts as a rule-of-thumb the practical international experience in dealing with abuse of dominance cases involving pharmaceuticals, where patents that block general competition are presumed to create market power.³⁸³

It is clear that patents do sometimes confer market power. This occurs in instances where effective substitutes to a patented product, or a product made using a patented process, do not exist. In such circumstances, the patent enables a manufacturer to set a supracompetitive price for a product, and so by definition confers market power.³⁸⁴

In contrast to other products, it is typical that patent protection for active ingredients, as well as some other patents, confers market power for pharmaceuticals. As an abundance of empirical studies make clear, absent price controls, patented pharmaceutical products are typically able to charge far more than 10 percent over the competitive price, a traditional benchmark for market power analysis. One broad-ranging study of the US market, where price controls are absent and generic substitution laws are moderately strong, found that in the first year after generic competition is introduced, patented products lose 44 percent of market share. The study found that pharmaceutical product prices fall on average 25 percent

³⁸³ See Section 2. In abuse of dominant position cases involving pharmaceuticals, the US antitrust authorities almost always define markets as consisting of a single product as defined by active ingredient (ATC5), and sometimes define the market as consisting only of a specific formulation of a single product, and then conclude that the patent owner in the market has market power. The European experience with abuse of dominance cases is more limited than in the United States, but there too the tendency in abuse of dominance cases is to define the market narrowly and then find market power in the narrow market.

³⁸⁴ Under the South African Competition Act, “ ‘market power’ means the power of a firm to control prices”. As explained in Section 2, the ability to profitably charge supracompetitive prices – typically referred to as “small but significant non-transitory increases in price” and more than 5-10 percent over competitive prices – defines the existence of market power under most elaborated guidelines of foreign competition authorities.

in the first year after generic competition is introduced,³⁸⁵ and prices continue to fall in subsequent years as more generic firms enter and the market moves to a more competitive price.³⁸⁶ Other studies have found comparable or greater price reductions over time.³⁸⁷

One important case of generic entry concerns Brazil. In 1996, Brazil became the first economically significant purchaser of generic ARV active pharmaceutical ingredients (APIs) and bulk products. By 1997, Brazil was providing HAART treatment. Initially, the generic prices (either locally manufactured or imported) were not significantly lower than the brand name/patent owner prices, but over time, generic prices fell significantly. In 1998 Brazil was paying more than \$25,000 per kilo for the generic APIs for d4T and about \$20,000 per kilo for 3TC APIs. By 1999 these prices had fallen to approximately \$8,000 for d4T and \$5,000 for 3TC. By 2003 these prices were closer to \$500 per kilo. For ARV products facing competition in Brazil, the finished product costs have continued to fall every year.³⁸⁸

Not all pharmaceutical-related patents confer market power; indeed, most do not. The key initial inquiry is whether the patent effectively blocks generic competition. Patents on active ingredients always block generic competition for the product. Process patents might³⁸⁹ or might not³⁹⁰ block generics from entering the market.

Where generics are able to enter the market, a subsequent inquiry is whether they are able to engage in effective competition with the patent-protected product. Where formulation, dosage or other patents block generics from competing effectively with the brand-name product, then the brand-name product continues to exert market power.³⁹¹ Whether these

³⁸⁵ Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998, 28.

³⁸⁶ According to the Congressional Budget Office study, with one to 10 generic firms in the US market, prices tend to fall about 40 percent. Above 10 firms, the price tends to fall by about two-thirds. When more than 20 firms enter the market, prices may fall by 80 percent. Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998, at 32. These estimates are based both on Congressional Budget Office calculations and those from Caves, Whinston and Hurwitz, *Patent Expiration, Entry and Competition in the US Pharmaceutical Industry*, Brookings Papers on Economic Activity: Microeconomics (1991) p. 36, table 9.

³⁸⁷ The PRIME Institute of the University of Minnesota has compiled data on generic penetration of the brand market in pharmaceuticals. According to their analysis, for most products, the best generic price was obtained about 30 months after the first generic entry into the market. In the Prime Institute analysis, the generic products entered the market about 27 percent below the brand price, and prices fell over time. After 30 months, generic prices were approximately 20 percent of the brand price. Stephen W. Schondelmeyer, *The Role of Generics in the US Pharmaceutical Market*, Presentation to the World Bank. June 24, 2003. Compiled by the PRIME Institute, University of Minnesota from data found in Kidder, Peabody. See also the Consumer Project on Technology analysis of reimbursement data from the Maryland Medicaid program for drugs that went off patent in the United States in 1996, James Love and Thiru Balasubramaniam, *The Effects of Generic Competition on Drug Prices Over Time* (Expert Report JL/TB(A)).

³⁸⁸ See James Love and Thiru Balasubramaniam, *The Effects of Generic Competition on Drug Prices Over Time* (Expert Report JL/TB(A)).

³⁸⁹ The process patent on Epogen, for example, has kept generic competitors off the market. See Andrew Pollack, *Two Paths to the Same Protein*, New York Times, March 28, 2000.

³⁹⁰ India, for example, has been able to develop a thriving generics industry, and features rapid introduction of generic products, with a patent system that awards process but not product patents. In countries that provide both process and product patents, there are numerous cases where product patents have not been sufficient to forestall generic competition.

³⁹¹ For example, the US Federal Trade Commission alleged that Biovail was able to exert market power over the market for Tiazac, a prescription drug taken once a day that combines both an immediate-release and an extended-release form of diltiazem, and generic versions of Tiazac, by virtue of a formulation patent that gave it

patents block effective generic competition is a fact-specific inquiry; but if it is found that they do, the presumption should be that the brand-name product maintains market power.

The mere existence of therapeutic alternatives, whether in ATC3 or ATC4, is not sufficient to rebut the presumption that a patent on an active ingredient or other patents blocking generic competition for a product, confers market power. Competition within a therapeutic class, whether from on-patent or generic products, can and typically does constrain firms' pricing power and prevent them charging pure monopoly prices, but the competitive constraints are generally not sufficient to prevent pharmaceutical patent holders from charging supracompetitive prices -- meaning small but significant amounts above competitive levels.³⁹² Indeed, even after other patented products are introduced into a therapeutic class, prices generally continue to rise in inflation-adjusted terms.³⁹³

Evidence that prices rise despite alternatives in a therapeutic class shows that individual patented products generally have market power. Another way of explaining the data is that each patented medicine competes in a distinct product market.³⁹⁴

Where generic competition is blocked, a pharmaceutical patent holder may rebut the presumption of market power by showing:

- (1) actual substitution between the patented product and others in the same therapeutic class; and
- (2) that actual and potential substitution is constraining the price charged by the patent holder; and
- (3) that the patent holder's price is less than a small but significant amount above the competitive price.

market power over branded and generic forms of diltiazem. Federal Trade Commission Complaint, *In the Matter of Biovail Corporation*, Docket No. C-4060, paragraphs 19-20, 2002, available at <http://www.ftc.gov/os/2002/04/biovailcomplaint.htm>.

³⁹² "Patents do not grant total monopoly power to companies in the pharmaceutical industry. In many cases, several chemicals can be developed that use the same basic mechanisms to treat a disease. Since a patent applies to a specific chemical or production process, different firms can end up patenting similar, competing drugs based on the same innovative principle. In addition, drug therapies often compete with nondrug therapies. Rather than having a pure monopoly, frequently drug companies produce slightly different products -- leading to a form of imperfect competition that allows an innovator firm to earn higher profits than it could in a perfectly competitive market but less than it would with a pure monopoly." Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998, 19.

³⁹³ "CBO examined the list prices of breakthrough and me-too drugs over time for five therapeutic classes. In four of the five, the list price of the breakthrough product continued to increase in real terms -- that is, by more than just the effects of inflation -- after the entry of one or more me-too products." Other studies of the US market, CBO reported, reached similar conclusions. Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998, at 20 [internal footnotes omitted].

³⁹⁴ "Price competition among similar innovator drugs is softened because products are differentiated," notes the US Congressional Budget Office. "It is also softened because entry in the pharmaceutical industry is limited by patent protection and the [regulatory] approval process." Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998, 21.

Such rebuttal evidence may be countered by evidence that drug prices within the therapeutic class are rising even as new products are introduced into the class, direct evidence that the patent holder is charging more than a small but significant amount above the competitive price, evidence that substitution is not available for significant subpopulations and any other relevant evidence.

Note that a finding that a patent holder is charging supracompetitive prices is not a condemnation. It is merely defining evidence of market power, which is not prohibited in the South African Competition Act, so long as it was legitimately obtained and not improperly wielded.

4.2 ESSENTIAL FACILITIES DOCTRINE

Section 8(b) prohibits dominant firms from refusing to give a competitor access to an essential facility when it is economically feasible to do so. An essential facility is defined in the act as an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers.

As explained in Section 2, the South African Competition Court of Appeals defined the basic elements of a claim under section 8(b) in *Glaxo v. National Association of Pharmaceutical Wholesalers*.³⁹⁵ The following proposed interpretations follow that exposition.

4.2.1 Resource Cannot Reasonably be Duplicated

4.2.1.1 Proposed Interpretations

A patent is a resource that cannot reasonably be duplicated when it covers a vital input for the creation of a product and there is no close actual or potential substitute for the input.

4.2.1.2 Commentary

A resource is not an essential facility if a close substitute for resource exists. Thus, the first element of essentiality requires that “the facility itself is indispensable to carrying on business, inasmuch as there is no actual or potential substitute for that facility.”³⁹⁶

Courts have held that the “inquiry into the practicability of duplicating the facility should consider economic, regulatory and other concerns.”³⁹⁷ A plaintiff must show “more than inconvenience, or even some economic loss”;³⁹⁸ the plaintiff must have “no realistic, economically practical alternative means” of obtaining the needed input.³⁹⁹

³⁹⁵ Case No: 15/CAC/Feb02.

³⁹⁶ *NDC Health and IMS Health Comp D3/38.044* (3 July 2001) para 70.

³⁹⁷ *Florida Fuels, Inc. v. Blecher Oil Co.*, 717 F. Supp. 1528, 1533 (S.D. Fla. 1989) (“Although expensive in absolute terms, the cost of duplication may be reasonable in light of transactions that would be duplicated and the possible profits to be gained.”).

³⁹⁸ *Twin Labs., Inc. v. Weider Health & Fitness*, 900 F.2d 566, 570 (2nd Cir. 1990).

³⁹⁹ *City of Malden*, 887 F.2d at 163 n.6 (case involving access to wholesale electricity); *cf Corsearch, Inc. v. Thomson & Thomson*, 792 F. Supp. 305 (S.D.N.Y. 1992) (holding that computer database was not an essential facility because plaintiff could build own database at an affordable cost); *Hecht*, 570 F.2d at 992-93 (“To be

Where a patent covers an active ingredient for a medicine, it will generally be true that the medicine will not be able to be produced without a licence to the patent. Patents are, as a matter of law, not duplicable.

It should be noted that, in many cases, intellectual property does not block the production of a specific product and therefore this test does not establish that every intellectual property right is an essential facility. Process or formulation patents, for example, will often not prevent competing products from entering the relevant market. Outside of the medicine context, most patents merely cover one element of a product that can be replaced with another input.⁴⁰⁰ A licence to intellectual property is only essential in the rare cases where it is truly a *vital* input.

4.2.2 Competitor Cannot Reasonably Provide Goods

4.2.2.1 Proposed Interpretations

- (i) *Lack of substitutes in relevant market.* Intellectual property that is a vital input for a product is an essential facility only if there are not close actual or potential substitutes in the relevant market that effectively compete with the product protected by intellectual property.
- (ii) *Needed medical products:* Where a licence for intellectual property is needed to produce a medical product that will contribute to addressing important public health concerns, there are no effective substitutes in the relevant market if
 - (a) existing medicines in the same therapeutic class are complements rather than substitutes for the product; or
 - (b) the product is an improvement over other products in terms of cost or therapeutic benefits to some patients; or
 - (c) public health authorities counsel that the specific medicine should be provided by the medical system to meet public health concerns.

4.2.2.2 Commentary

Whereas the first element of essentiality focuses on potential substitutes for the facility, the second inquiry focuses on potential substitutes for the product produced with the facility. Even where a patent blocks production of a particular product, the patent will not be an essential facility if there are sufficient substitutes for that product such that competition can restrain market power of the patent holder without access to the patent. Thus, courts have sometimes described this element of the essentiality inquiry as focusing on whether refusal of access to the facility is “likely to eliminate all competition on the part of that undertaking.”⁴⁰¹

‘essential’ a facility need not be indispensable; it is sufficient if duplication of the facility would be economically infeasible and if denial of its use inflicts a severe handicap on potential market entrants.”).

⁴⁰⁰ *Cf. Northern Pacific v. United States*, 356 US 1, 10 n.8 (1958) (“It is common knowledge that a patent does not always confer a monopoly over a particular commodity. Often the patent is limited to a unique form or improvement of the product and the economic power resulting from the patent privileges is slight.”); *accord SCM Corp. v. Xerox*, 645 F.2d 1195, 1203 (2d Cir. 1981) (stating that a patented product often “represents merely one of many products that effectively compete in a given product market”).

⁴⁰¹ *Oscar Bronner v. Mediaprint* [1998] ECR. I-7791 para 38; *see also NDC Health and IMS Health*, para 70.

Where other products are effective substitutes – i.e. the product is “close enough to the examined good that it becomes a substitute when the price of the examined good rises significantly above its cost”⁴⁰² – then access to a facility may not be necessary to ensure that market forces benefit consumers, even if the facility is a vital input for the production of some good.⁴⁰³

It should be conclusively determined that there are no substitutes for the product when facts analogous to the *Magill* case are present, i.e. the complainant seeks to introduce a new product onto the market that offers potential consumer benefits and the dominant firm(s) do not provide that product. In defining whether adequate substitutes for a particular product exist, it is appropriate to analyse the market “from the standpoint of the consumer – whose interests the statute was especially intended to serve”.⁴⁰⁴ Thus, courts have found that a product is unique to consumers when it provides “convenience and flexibility” at a lower cost, as in the case of the combination ski ticket in *Aspen*⁴⁰⁵ and the combination TV listings in *Magill*.⁴⁰⁶

In cases involving medicines, a product may have no close or actual substitutes because it is “different in terms of chemical composition, safety, efficacy, and side effects”.⁴⁰⁷ Medicines in the same therapeutic class, even at the ATC4 level, are not necessarily substitutes. This is particularly true when treatment requires combinations of medicines and therefore other medicines in the same class are “a complement . . . rather than their competitor.”⁴⁰⁸ In deciding whether a particular medicine is a substitute, it is appropriate to consider the opinions of medical experts and public health authorities.

⁴⁰² Hovenkamp at 4-41.

⁴⁰³ If, for example, consumers select Tylenol if Advil is priced 5-10% over its marginal cost, and vice versa, then the essential facility doctrine will be inapplicable, even if the active ingredient in each medicine was patented. If, on the other hand, a significant number of consumers can only benefit from the active ingredient in Tylenol, despite Advil being in the same therapeutic class, and the active ingredient in the medicine is patented, then both elements of the essentiality inquiry may be met.

⁴⁰⁴ *Jefferson Parish Hosp v Hyde*, 466 US 2, 15 (1984).

⁴⁰⁵ *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 US 585 (1985).

⁴⁰⁶ *Radio Telefis Eireann v Commission of the EC* [1995] ECR. I-743. See discussion of cases in Section 2.

⁴⁰⁷ Federal Trade Commission Complaint, *In the Matter of Abbott Laboratories and Geneva Pharmaceuticals, Inc.* Docket No. C-3946, 2000, <http://www.ftc.gov/os/2000/03/abbottcmp.htm>; see also Federal Trade Commission Complaint, *In the Matter of Asahi Chemical Industry Co., Ltd.*, 2000 <http://www.ftc.gov/os/2000/12/fmcasahicomplaint.htm> (“Other binders are not acceptable substitutes for pharmaceutical MCC for several reasons, including differences in quality, consistency, performance, efficacy, and stability.”).

⁴⁰⁸ Opinion of Mr Advocate General Warner, *Istitutio Chemioterapico Italiano and Commercial Solvents Corporation* [1974] ECR. 223 (discussing need for combination treatment for tuberculosis), quoted in Opinion of Mr Advocate General Jacobs delivered on 28 May 1998, *Oscar Bronner GmbH & Co. KG v Mediaprint*, [1998] ECR I-7791, para 60.

4.2.3 The Dominant Firm Refuses Access

4.2.3.1 Proposed Interpretations

The definition of “competitor” should include potential and downstream competitors.

A refusal of access should be deemed established when the holder of a patent constituting an essential facility has not instituted a nondiscriminatory, nonexclusive, standard-form licensing programme on reasonable terms, such as that available under the “licences of right” provisions of the Patent Act.

4.2.3.2 Commentary

There is no definition of “competitor” in the Act. Following the EC and US jurisprudence, this term should be read broadly to include potential competitors prevented from entering the market as well as customers that perform downstream sales or distribution functions that may impact the dominant firm’s market power, even if the refusing firm is not itself a participant in that market.⁴⁰⁹ The term should include, for example, a pharmacy, hospital or other medicine distributor that is prevented from selling or distributing generic products where the refusal thereby “extends, preserves, creates, or threatens to create significant market power in some market”.⁴¹⁰

Where access to a facility is essential to maintain competition, a refusal of access can be found where the owner fails to “actively promote competition”.⁴¹¹ In the context of intellectual property laws, competition can be actively promoted through an open licence, i.e. a nondiscriminatory, nonexclusive standard-form licence, such as that available through the South African Patent Act’s “licences of right” provision.⁴¹²

⁴⁰⁹ See, e.g., *United Brands United Brands and Commission of the EC* [1978] ECR. 207, discussed in Section 2.

⁴¹⁰ *York Timbers Limited and South African Forestry Company Limited*, Case Number: 15/IR/Feb01, at para 93.

⁴¹¹ *Advocate General’s opinion in Oscar Bronner* Para 34.

⁴¹² Section 53 of the Patent Act states:

- (1) At any time after the date of the sealing of a patent, the patentee may apply to the registrar for the patent to be endorsed with the words “licences of right” and where such an application is made the registrar shall, if satisfied that the patentee is not precluded by contract from granting licences under the patent, cause the patent to be endorsed accordingly.
- (2) Where a patent has been endorsed under this section—
 - (a) any person shall at any time thereafter be entitled as of right to a licence under the patent upon such conditions as may, in default of agreement, be decided by the commissioner on the application of the patentee or the person requiring the licence;
 - (b) the commissioner may, on the application of the holder of any licence granted under the patent before the endorsement, order such licence to be replaced by a licence to be granted by virtue of the endorsement on conditions to be decided by the commissioner;
 - (c) No interdict shall, in proceedings for infringement of the patent (otherwise than by the importation of goods) be granted against the defendant if he undertakes to take a licence upon conditions to be decided by the commissioner, and the amount, if any, recoverable from the defendant by way of damages shall in such case not exceed double the amount which would have been payable by him as licensee if such a licence had been granted before the earliest infringement;
 - (d) the renewal fee payable in respect of the patent after the date of the endorsement shall be one half of the renewal fee which would have been payable if the patent had not been so endorsed.

4.2.4 Economic Feasibility

4.2.4.1 Proposed Interpretations

Where the refusal of a patent holder to licence a patent restricts access to needed medicines, it should be conclusively determined that it is economically feasible to grant a licence at reasonable royalties.

4.2.4.2 Commentary

The final consideration in an essential facilities case is whether it is economically feasible for the property holder to grant access on non-discriminatory terms. It is traditionally the burden of the respondent to present evidence showing that it is not economically feasible to grant access to an essential facility. This burden normally requires the respondent to show that providing access to the facility would impede the dominant firm's ability to serve its customers or would otherwise harm consumer welfare.

A mere loss of profits on the part of the dominant firm is not a legitimate justification for refusing access to an essential facility.⁴¹³ A business justification defence is valid only "if it relates directly or indirectly to the enhancement of consumer welfare," not to the mere enhancement of the economic welfare of the dominant firm.⁴¹⁴

Unlike granting access to tangible property, granting access to intellectual property has very low, if any, direct economic costs to the property owner. Thus, one may conclude that a duty to licence intellectual property arises under the essential facility doctrine whenever it is necessary for competition in the relevant market under the first three factors.

Most courts have taken a broader view of feasibility constraints when intellectual property is at stake.⁴¹⁵ It is well recognized that intellectual property laws grant exclusive rights to create incentives to innovate for the benefit of society. A broad rule that all intellectual property that impedes competition must be licensed may reduce incentives for future innovation. Based on this premise, courts in the US and EC have ordered access to intellectual property only where certain special circumstances harming consumer welfare exist.

In developing countries, reduced access to needed medicine from exclusionary use of intellectual property rights should be recognized as a special circumstance justifying licensing duties, although this effect is rare in high income countries with advanced health insurance systems. As described more fully in section 4.3, discussing section 8(c) of the Competition Act, a strong presumption that it is economically feasible to licence medicine patents at reasonable royalty rates is justified by a consumer welfare maximizing approach to interpreting the Competition Act. The costs to society, in terms of a substantial reduction in

Section 53(7) states: "Every endorsement of a patent in terms of this section shall be recorded in the register and shall be advertised in the journal and in such other manner as the registrar may direct, to bring the endorsement to the notice of interested persons."

⁴¹³ See *Otter Tail v. United States*, 410 US 366, 380 (1973) ("The promotion of self-interest alone does not invoke the rule of reason to immunize otherwise illegal conduct.").

⁴¹⁴ *Data General Corp. v. Grumman Sys.*, 36 F.3d 1147, 1183 (1st cir. 1994)

⁴¹⁵ See discussion of cases in Section 2.

access to needed medicines, cannot be justified by the negligible incentives to innovate that allowing refusals to licence patents in most poor countries can provide.⁴¹⁶

There is ample evidence that a royalty rate of between 2-8% annual sales is a reasonable compensation term for foreign production of a patented pharmaceutical product.⁴¹⁷ This evidence should be used to create a heavy presumption that it is “economically feasible” for a patent holder to licence its intellectual property in a pharmaceutical product at rates within this range.

4.3 EXCLUSIONARY ACT

Section 8(c) prohibits dominant firms from engaging in an exclusionary act if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain. An exclusionary act is defined as an act that impedes or prevents a firm entering into, or expanding within, a market.

4.3.1 Act Impedes Entering or Expanding within a Market

4.3.1.1 Proposed Interpretations

- (i) A refusal of a dominant firm to grant a licence for intellectual property is an exclusionary act if the licence is needed to produce a competing product.
- (ii) A refusal to licence should be deemed established where the evidence shows that the intellectual property right holder was not willing to deal on reasonable and non-discriminatory terms, including where:
 - (a) a licence is not granted within a reasonable time (e.g. 150 days) after a request with reasonable terms, or
 - (b) patterns of dealing suggest that right holder’s negotiation was not bona fide, or
 - (c) statements by company representatives indicate animus toward licensee.

⁴¹⁶ See Expert Reports of Juan Rovira, F. M. Scherer, Aiden Hollis and William Jack.

⁴¹⁷ See James Love, *Setting Reasonable Royalties for Nonvoluntary licences* (Appendix) (discussing Japanese royalty guidelines that range from 0-6%); F. M. Scherer (describing royalty rates in the US). According to a February 2000 submission to the United States Trade Representative (USTR) by the US trade group PhRMA, five percent is the “average pharmaceutical royalty rate.” PhRMA’s submission is consistent with the recent presentation by Q. Todd Dickenson, former Director of the US Patent and Trademark Office and Undersecretary of Commerce, at the October 2002 meeting of the Trans Atlantic Consumer Dialogue’s Committee on Intellectual Property. According to Mr. Dickenson, a royalty payment of “about 4% . . . is a very standard royalty across all industries. Most royalties run between two and five percent.” The United Nations Development Programme, in its 2001 Human Development Report (108), noted that Canada’s compulsory licensing scheme for pharmaceutical products “used to pay royalties of 4%” and recommended that “Developing countries could award an extra 1-2% for products of particular therapeutic value and 1-2% less when R&D has been partially covered by public funds.” The licence of right recently announced by Pharmacia Corp. for delavirdine (aka Rescriptor) is based on a 5% royalty standard. During the 1980s, Singapore routinely granted compulsory licences for government use of patented pharmaceuticals with a 5% cap on royalties. In 1997, the Philippines Supreme Court approved a compulsory licences for the cimetidine patents with compensation of 2.5 percent of the generic sale price. Other cases have used much higher royalty rates. The UK, for example, habitually awarded rates in excess of 20% and the result, according to F.M. Scherer, was a limited benefit to consumers.

4.3.1.2 Commentary

In our interpretation of the Competition Act, 8(c) differs from 8(b) in a refusal to licence case in that the essential facility doctrine in 8(b) requires affirmative action on the part of the dominant firm to promote competition, whereas section 8(c) requires the finding of a specific “exclusionary act”. Thus, in 8(b) we propose that a “refusal of access” can be found through a failure to take affirmative action to promote competition through open licensing. Under 8(c), we believe it is necessary to show that there has been a specific refusal to licence in response to a reasonable request.

Although we believe it is necessary to prove a specific refusal to licence under 8(c), “there need not be an outright refusal” to prove this element of the claim.⁴¹⁸ It should be sufficient to prove that an exclusionary act has taken place where the evidence, taken as a whole, indicates unwillingness on the part of the dominant firm to deal with the requesting party on reasonable and nondiscriminatory terms.⁴¹⁹

In most cases, it will be sufficient to find a refusal where a licence is not granted within a reasonable time from a request that includes reasonable terms. The policy reason for imposing such a requirement is that the longer issuance of licenses is delayed “the less time licensees have to recover their startup costs and the more difficult it is to achieve effective competition among multiple generic substitute suppliers.”⁴²⁰

There is no reason for protracted negotiations over licences that grant only the right to produce and market a competing product. Generic medicines can be marketed under different trade names to maintain separate corporate identities. In addition, quality control for medicines is accomplished through government regulatory agencies, not by the patent holder.

A lack of capacity of the licensee to immediately produce the patented article is not a legitimate justification for denying a licence. In Canada from 1969-1992, any person could apply for a compulsory license for a needed medicine, “and there were no qualifications to be met. Applicants did not even have to prove that they were capable or competent to exploit the license or handle pharmaceutical products.”⁴²¹ Thus, some licence recipients in Canada “did not follow through by actually supplying the drug in Canada” and this was not seen as a causing any harm to consumers.⁴²²

As Carlos Correa explains in his expert report, a standard that licences should be issued within 150 days after an initial request has been deemed reasonable in the legislation of some countries.⁴²³ As discussed above in the section on the essential facilities doctrine, the royalty rate offered should be considered reasonable if it is between 2-8% of the licensee’s sales.

⁴¹⁸ *Delaware & Hudson Ry. Co. v. Consolidated Rail Corp.*, 902 F.2d 174, 179-180 (2d Cir. 1990) (finding refusal where “the terms of the offer to deal are unreasonable”).

⁴¹⁹ *Fishman v. Wirtz*, 807 F.2d 520 (7th Cir. 1986) (“Agreeing to deal on unreasonable terms is merely a type of refusal to deal.”).

⁴²⁰ F.M. Scherer Expert Report.

⁴²¹ Reichman and Hasenzahl, *The Canadian Experience* at 35.

⁴²² F.M. Scherer Expert Report.

⁴²³ See Carlos Correa Expert Report (explaining Argentina’s law allows a compulsory licence if a request is not granted within 150 days of the request; Chinese law allows a compulsory licence when “requests for

While the presumption based on time from the initial request on reasonable terms should be sufficient to prove the refusal element in most cases, a complainant should, of course, also be free to establish a refusal through other circumstantial or direct evidence demonstrating that the patent holder was not willing to deal on reasonable non-discriminatory terms.

4.3.2 Anti-Competitive Effect Outweighs the Pro-Competitive Gain

4.3.2.1 Proposed Interpretations

The anticompetitive effect, in terms of human, social and economic costs, of a refusal to licence should be presumed to outweigh any technological, efficiency or other pro-competitive gain whenever:

- (a) the product is necessary to meet a recognised public health concern; and
- (b) is not being used by a substantial number of people who need it; and
- (c) the product is
 - (1) not available by any firm because of the refusal to licence; or
 - (2) not available from all potentially qualified suppliers and the price by the patent holder is above that which would result in a competitive market with reasonable royalty rates paid to the patent holder.

4.3.2.2 Commentary

Liability under the exclusionary acts doctrine turns on a balance between the costs and benefits associated with the act. Courts commonly analyse the anticompetitive effect of an action in terms of harm to the competitive process as well as harm to consumer welfare that the competitive process is meant to protect.⁴²⁴ The South African Competition Act and its legislative history spell out the range of anticompetitive effects it seeks to thwart in detail. The Act is intended to create a competitive economic environment:

- “focussed on development”⁴²⁵
- “to provide consumers with competitive prices and product choices”⁴²⁶
- “to . . . advance the social and economic welfare of South Africans”⁴²⁷
- “to correct structural imbalances and past economic injustices”⁴²⁸

authorization . . . have not been successful within a reasonable time”; German law allows a compulsory licence if “the applicant has unsuccessfully endeavoured during a reasonable period of time to obtain” a licence). *See also* TRIPS Section 31 (authorizing compulsory licences if “the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time”).

⁴²⁴ *See Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 US 585 (1985) (examining a refusal to deal’s “impact on consumers and whether it has impaired competition in an unnecessarily restrictive way” and finding the refusal to deal illegal in part because consumers were prevented from purchasing a “superior” 4-area ski ticket that “provided convenience and flexibility”); *Radio Telefis Eireann v Commission of the EC* [1995] ECR. I-743 (finding special circumstances warranting a compulsory licence to exist where consumers were prevented from purchasing a less expensive combination TV guide from the complainant).

⁴²⁵ Competition Act, Preamble.

⁴²⁶ Competition Act, Section 2.

⁴²⁷ Competition Act, Section 2.

- “to reduce the uneven development, inequality and absolute poverty which is so prevalent in South Africa.”⁴²⁹

Where the refusal at issue is for a licence for a needed health care product, the central balance called for under Section 8(c) of the Act will be the (a) the anticompetitive effect of a refusal to licence a patent in terms of *reduced access to a needed treatment*, weighed against (b) the *reduced incentives to innovate* that may accompany a compulsory licence.

The standards we propose flow from the purpose of patent rights. Governments grant patent rights out of the belief that increased profits from intellectual property protection may stimulate future innovation. It is widely recognized, however, that incentives to innovate will not flow equally from intellectual property protection in every country and that in many individual cases the harm to consumers from intellectual property protection will outweigh any benefit in terms of increased incentives to innovate.⁴³⁰

As Professor Hollis describes, the most relevant anticompetitive effect from a refusal to licence is “is that some consumers who would have bought at the competitive price do not buy it at the monopoly price”. This effect, which is called “deadweight loss” by economists, “is an entirely negative outcome, since the firm does not profit from these consumers, and the consumers are worse off” for lack of access to the product.

For these reasons, the TRIPS agreement recognises the power of every country to grant compulsory licences, particularly noting the appropriateness of this tool for public health reasons. Under a compulsory licence, the government authorises competitors to use the patent holder’s invention in exchange for payment of a royalty. This may have the effect of lowering the profits of the intellectual property holder which may in turn lower incentives to innovate in the future.

Choosing to compulsory license therefore involves a difficult trade-off between consumer benefits today (through lower prices) and consumer benefits in the future (through greater innovation). Compulsory licensing becomes desirable when the former is much greater than the latter.⁴³¹

Thus Professor Hollis recommends that “one articulation of a standard under section 8(c) for finding a violation through a failure to licence competitors -- triggering the remedy of a

⁴²⁸ *Proposed Guidelines for Competition Policy: A Framework for Competition, Competitiveness and Development*, Department of Trade and Industry 2.4.11 (27 November 1997).

⁴²⁹ *Proposed Guidelines for Competition Policy: A Framework for Competition, Competitiveness and Development*, Department of Trade and Industry 10.1 (27 November 1997).

⁴³⁰ See F. M. Scherer, *Global Welfare in Pharmaceutical Patent Policy* (2003) (using an economic model to show that global welfare is maximised by allowing poor countries to access generic affordable medicines “over a wide range of negative new product development impacts if one accepts the reasonable premise that the marginal utility of income is appreciably higher in poor nations than rich nations”); Reichman Report at 34 (“While [US] precedents . . . clearly reveal the deference shown to intellectual property owners in the United States, there is no reason to assume that an equally deferential or protectionist approach would benefit developing countries. In those countries, fairness and the ability of local firms to enter markets may legitimately outweigh concerns about incentives to innovate, at least until per capita GDP reaches fairly high levels.”); see also KEITH MASKUS, *INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY* (2000); J. H. Reichman, *Taking the Medicine, with Angst: An Economist’s View of the TRIPS Agreement*, 4 J.I.E.L. 795.

⁴³¹ Hollis Expert Report.

compulsory licence -- would be when the consumer benefit from lower prices today is greater than the future consumer benefits in the form of increased innovation that would result from maintenance of the monopoly price.”

4.3.2.3 The Anticompetitive Effect of Reduced Access to Needed Medicines

The anticompetitive effect from refusing to allow competition in the sale of needed medicines can be massive. Lack of health in a population can cause debilitating social and economic downward spirals that escalate negative effects throughout society.⁴³² This “deadweight loss” exists whether or not there is a private market for the medical product in question. Even where the only market for the product is through the public health system, access to care will be rationed by refusals of a medical product patent holder to allow competition for the supply of the system.⁴³³

In estimating the cost of a refusal to licence in terms of restricted access to medicine, no exact figure of the number of people excluded by reason of the refusal to licence competition will be possible. Nonetheless, it should be presumed that the refusal to licence has the effect of excluding a significant portion of the population from receiving needed treatment whenever the product is not being taken by a substantial number of people who need it because (a) it is not available on the market because of the refusal to licence,⁴³⁴ or (b) the price of the product restricts access and full competition is not permitted in the market by the patent holder.

4.3.2.4 Incentives to Innovate

Once it is established that there is a substantial anticompetitive effect, in the form of unnecessary morbidity and mortality from lack of access to needed medicines, a presumption that this effect outweighs the incentives to innovation gained from the exclusionary practice is appropriate. Such a presumption would be consistent with numerous public health grounds for compulsory licences in countries throughout the world.⁴³⁵

There are several reasons why the presumption is appropriate that the lack of access to medicines attributed to a failure to licence competitive suppliers outweighs any consumer benefits from incentives to innovate that the exclusionary act may create is appropriate. First, it may be presumed that incentives to produce needed medicines will not be substantially reduced by a competitive market in South Africa because the market for medicines is global and the demands of developing countries play little role in inducing investments in R&D

⁴³² See Iris Boutros Expert Report, *The Socio-Economic And Demographic Impact Of The HIV/AIDS Epidemic in South Africa*.

⁴³³ See Hollis Expert Report.

⁴³⁴ This may be because a situation similar to that in the *Magill* case is present where a failure to cross-licence intellectual property prevents a new product from coming on the market.

⁴³⁵ See CARLOS CORREA, INTEGRATING HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 94 (South Centre 2000) (reporting that French law authorises compulsory licences when medicines are “only available to the public in insufficient quantity or quality or at abnormally high prices”); Jerome Reichman Expert Report (describing history of compulsory licensing, including specifically to increase access to affordable medicines); F.M. Scherer Expert Report (describing section 41 of the UK Patent Act of 1949 that created “a rebuttable presumption in favor of compulsory licensing” to ensure that food, medicine and surgical devices were “available to the public at the lowest prices consistent with the patentees’ deriving reasonable advantage from their patent rights”).

regardless of intellectual property protection. This fact was recently explained by the UK Commission on Intellectual Property Rights:

Pharmaceutical research by the private sector is driven by commercial considerations and if the effective demand in terms of market size is small, even for the most common diseases such as TB and malaria, it is often not commercially worthwhile to devote significant resources to addressing the needs. . . . Given that private companies have to be primarily responsible to their shareholders, this necessarily leads to a research agenda led by the market demand in the markets of the developed world, rather than by the needs of poor people in the developing world, and thus a focus mainly on non-communicable disease.

Regardless of the intellectual property regime prevailing in developing countries, in reality there is little commercial incentive for the private sector to undertake research of specific relevance to the majority of poor people living in low income countries. Accordingly, little such work is done by the private sector. . . . Where diseases are common to both developed and developing countries, the picture is different. Thus, there is significant private sector R&D on HIV/AIDS. This contrasts with the limited work on tuberculosis and malaria, and virtually none on diseases such as sleeping sickness. . . .

So what role does IP protection play in stimulating R&D on diseases prevalent in developing countries? All the evidence we have examined suggests that it hardly plays any role at all, except for those diseases where there is a large market in the developed world (for example, diabetes or heart disease). . . . The heart of the problem is the lack of market demand sufficient to induce the private sector to commit resources to R&D. Therefore, we believe that presence or absence of IP protection in developing countries is of at best secondary importance in generating incentives for research directed to diseases prevalent in developing countries.⁴³⁶

A similar conclusion was stated by Professor William Jack in his report prepared for this case:

For drugs like those that are the subject of the Complaint, with global markets – that is, with potential consumers in both rich and poor countries – monopoly prices in poor countries are unlikely to constitute a large share of world-wide profits for the patent holder. It is therefore the contention of this analysis that any reduction in profits from South African sales [at low royalty rates] (which would, in any case, be limited due to a resulting expansion in sales volume) would not have a significant effect on world-wide firm profits, and thus would be unlikely to deter future R&D investment for drugs with global markets.

Another reason for the presumption against the patent holder, at this stage of the analysis, is the particular structure of demand in markets for needed medicines in countries with high inequality. As Professor Hollis explains, these markets have a tendency to exhibit demand curves that reflect inequality of wealth. Convex demand curves create incentives for patent

⁴³⁶ UK Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* 32-33 (2002).

holders to set very high prices for their products, serving only the very highest income earners to the detriment of the great majority of the population. In such cases, “welfare will not be well-served by the patent system . . . , since the incentive effects of patent protection (the profits) are relatively small compared to the deadweight losses. That is, patent protection will do little to stimulate innovation, but will seriously harm welfare.”⁴³⁷

Using a similar analysis, Professor Jack notes that profits of the patent holder may not be significantly affected by expanding competition for lower priced medicines because the patent holder may continue to market its goods in the same high income market it is already serving. Professor Jack concludes that it is reasonable to conclude that, whenever a significant percentage of the population is left unserved by a patent holder, the “failure to permit generic producers to supply the price-sensitive segment of the private market may be motivated by an anti-competitive desire to preclude competitors from gaining a foothold in the low-end of the market that would erode the market power the patent holder would otherwise enjoy after the expiration of the patent.”⁴³⁸

For these reasons, both Professor Jack and Professor Hollis recommend that the Competition Act be interpreted to authorise compulsory licences whenever the price of needed medicines is higher than a competitive market would produce and the result is a significant number of people who cannot afford treatment. “In such cases,” explains Professor Hollis, “it can be confidently and conclusively presumed that ‘the anti-competitive effect’ of the failure to licence all qualified suppliers – the deadweight loss represented by South Africans who will die from AIDS that otherwise would have lived – far outweighs the ‘technological, efficiency or other pro-competitive gain’ to consumers in terms of future innovation incentives from the maintenance of monopoly pricing power.”⁴³⁹

⁴³⁷ Aidan Hollis Expert Report.

⁴³⁸ William Jack Expert Report.

⁴³⁹ See also F. M. Scherer, *Global Welfare in Pharmaceutical Patent Policy* (2003) (concluding from an economic analysis that, even with no royalties paid to the patent holder, “global welfare is maximised by letting low-income nations free-ride on the patented inventions of first-world nations over a wide range of negative new product development impacts if one accepts the reasonable premise that the marginal utility of income is appreciably higher in poor nations than rich nations”).

SECTION 5: EVALUATION

5.1 DOMINANCE

Both GSK and BI are dominant in the relevant markets. These markets should be defined as the South African product market for the manufacture and sale of AZT, the manufacture and sale of 3TC, the manufacture and sale of Combivir and the manufacture and sale of NVP. GSK meets the statutory numerical test for dominance in the product market for the manufacture and sale of AZT, the manufacture and sale of 3TC and the manufacture and sale of Combivir. BI meets the statutory numerical test for dominance in the product market for the manufacture and sale of NVP.

GSK displays market power for AZT, 3TC and Combivir, and BI displays market power for NVP. This finding obviates the need to define markets and determine market share. Defining market share is only a proxy for determining the presence or absence of market power, and under the Competition Act, the possession of market power is determinative of dominance. Both GSK and BI control patents that block generic competition for their respective products, and thus possess market power. This conclusion is buttressed by substantial economic evidence particular to the products at issue in this case.

5.1.1 Market Definition

5.1.1.1 Geographic Market

In the merger between *Glaxo Wellcome plc and Smithkline Beecham plc* (case no. 58/AM/May00), the Competition Tribunal accepted the EC rule that “the geographic market for pharmaceutical products is national in scope” because the sale of pharmaceutical products is influenced by national policies, and prices and product differentiation vary between countries. The finding that pharmaceutical markets are national in scope is particularly apt in South Africa where distributors must be a registered South African company, registration of medicines is conducted on a national scale and all of the medicines subject to the complaints are covered by South African patents that allow the respondents to exclude other competitors from the South African market.

5.1.1.2 Product Markets

The product market or markets are for the manufacture and sale of AZT, 3TC, Combivir and NVP. The relevant ATC3 classification for AZT, 3TC, Combivir and NVP is for Direct Acting Antivirals under the WHO classification, and HIV Antivirals under the EphMRA system.⁴⁴⁰ In this case, reliance on the ATC3 classification would be misplaced. For HIV-infected persons in Stage 4, for some in Stage 3, and for smaller numbers in Stage 2 and Stage 1, WHO Guidelines and standard treatment protocols worldwide call for treatment with triple-drug therapies. These drugs are drawn from separate subcategories -- ATC4 classifications -- and there is limited ability to substitute between them.⁴⁴¹

⁴⁴⁰ www.whooc.no/atcddd/indexdatabase; www.ephmra.org/atc/6_000.html

⁴⁴¹ See WORLD HEALTH ORGANISATION, SCALING UP ANTIRETROVIRAL THERAPY IN RESOURCE-LIMITED SETTINGS 28 (2002) (“The recommended regimens each contain a dual nucleoside component (backbone) to be combined with a PI, an NNRTI or the potent NsRTI, abacavir (ABC).”).

There is significant therapeutic substitutability among products within the ATC4 groups. Within the NRTI group, for example, AZT and d4T may generally be substituted. Within the NNRTI group, NVP and EFZ may generally be substituted. This potential substitution does not, however, render the ATC4 classification an appropriate market for market power analysis.

Substitution between drugs within ATC groups does not render the markets competitive at this level. Within the ATC4 subclasses, each drug has different enough properties that they are not fully substitutable. “Because of the matrix of interconnected factors relating to toxicity and effectiveness of treatment, access to a wide choice of ARVs is required in order to effectively administer HAART. At present, no single registered ARV is fully substitutable by another.”⁴⁴²

For specific groups of people, some of the options within the ATC4 subclass are completely precluded. For example, within the subclass of NNRTI, there are only two products, EFZ and NVP.⁴⁴³ Clinical guidelines proscribe prescription of EFZ for women of childbearing age⁴⁴⁴ - leaving only a single product in the subgroup for this large category of persons. EFZ is also not available in paediatric formulation, and is contra-indicated for children under three,⁴⁴⁵ and is contraindicated for HIV-2 infected persons.⁴⁴⁶ The same is true for other specific choices within subclasses.⁴⁴⁷

Because of the complexity of ARV treatment, and the need to combine three different products, with each combination affording distinct advantages and disadvantages, “there is no single ARV regimen which will be ideal for either all patients or all clinical situations. Therefore, it is necessary to have access to a combination of drug choices both within and between drug classes.”⁴⁴⁸

Patients will need more than one drug in a class. Because of treatment failure, side effects and other clinical complications, over time patients will need to move to second-line regimens, with a recommendation that each drug in the regimen be switched. This means, for example, that while patients may be able to choose AZT over d4T as an initial therapy, over time most patients will need access to both. This inhibits patients’ ability to switch back-and-forth between therapies in light of price differences.⁴⁴⁹

⁴⁴² Affidavit of Dr. Robin Wood, 13; For a review of specific side effects for ARVs, see WHO, SCALING UP, 85-94.

⁴⁴³ A third NNRTI, delavirdine, is not recommended, because of pill burden and thrice-daily dosing. WHO, SCALING UP, 31.

⁴⁴⁴ WHO, SCALING UP, 31-32, 41.

⁴⁴⁵ WHO, SCALING UP, 66

⁴⁴⁶ WHO, SCALING UP, 107

⁴⁴⁷ See WHO, SCALING UP, 106 (explaining that the d4T-ddI coupling is contraindicated for NNRTI-based combinations for tuberculosis-co-infected persons); WHO, SCALING UP at 28 (“Cautions have been raised about the ddI-d4T coupling’s potential to cause lactic acidosis, particularly in pregnant women, hepatotoxicity and neurotoxicity (both peripheral neuropathy and a condition resembling the Guillain-Barre syndrome”).

⁴⁴⁸ Affidavit of Dr. Robin Wood, 9.

⁴⁴⁹ In the case of EFZ and NVP, “the almost complete cross-resistance between EFZ and NVP means that a switch between the two agents in the setting of treatment failure is not advisable.” In this instance, patients who need to switch regimens must switch out of the class. WHO, SCALING UP, 37.

In short, people with HIV/AIDS need access to the entire range of ARVs. As the WHO's 12th Expert Committee on the Selection and Use of Essential Medicines concluded:

While accepting that there were many circumstances in medicine where one essential drug may substitute easily for other members of a class, thus allowing the placement of a single agent on the Model List (with appropriate advice about substitution), this was not possible with HIV treatment. Effective therapy requires commencement of three drugs simultaneously, and alternative regimens are necessary to meet specific requirements at start-up, to substitute for first-line regimens in the case of toxicity, or to replace failing regimens. The committee considered various approaches to the listing of these agents but agreed finally that if they were to be listed, all drugs recommended should be included in the Model List.⁴⁵⁰

Accordingly, the relevant product markets should be defined as the market for manufacture and sale of AZT, the market for manufacture and sale of 3TC, manufacture and sale of Combivir,⁴⁵¹ and the market for manufacture and sale of NVP. This conclusion is buttressed by the economic analysis considered below in assessing the market power of each of the products.

5.1.2 Market Shares

Under the Competition Act's market shares approach to determining dominance, each of the respondents is dominant in the relevant market if the ATC5 level of classification is used as the relevant market. Because no other products with the same active ingredients are on the market in South Africa, GSK has a 100 percent share of the AZT market, a 100 percent share of the 3TC market and a 100 percent share of the Combivir market. Similarly, BI has a 100 percent share of the NVP market.

As shown in the tables below, GSK remains dominant under a market shares approach even if the relevant market is defined at the ATC3 level (Direct Acting Antivirals/ HIV Antivirals), because its market share exceeds 45 percent. GSK has a 46.77 percent share by revenue for the 12 months ending in June 2003.⁴⁵² This is the company's share for the three products which are subject of this investigation (AZT, 3TC and Combivir (AZT+3TC)).

Based solely on market share, BI is not dominant in the ATC3 market. For its single product of NVP, BI had a 11.15 percent share.⁴⁵³ Based solely on market share, BI is presumptively

⁴⁵⁰ 12th Expert Committee on the Selection and Use of Essential Medicines Meeting, 15-19 April 2002, Annexure F to Statement of Complaint.

[REDACTED]

⁴⁵¹ As the combination of AZT and 3TC, Combivir is a highly desirable product because of it simplifies regimens and improves adherence. WHO, SCALING UP, 31. For all of the reasons that AZT and 3TC should be considered separate markets, so should Combivir. It is an effective substitute only for AZT and 3TC.

⁴⁵² Market share data from IMS.

⁴⁵³ Market share data from IMS. [REDACTED]

dominant in the ATC4 NNRTI market, because its market share is above 35 percent but below 45 percent. Using an ATC4 category, the market participants in the NNRTI market are BI and Merck. BI has a 35.14 percent share in this market.⁴⁵⁴

Table 6: Market Shares: All ARVs (12 Months Ending June 2003)

Drug	Revenue (Million Rand)	Percent of total revenues
NRTI		
Combivir (3TC + AZT)	61.8	35.33
3TC (3TC)	11.7	6.69
Retrovir (AZT)	8.3	4.75
Videx (ddI)	18.2	10.41
Zerit (d4T)	4.8	2.74
NNRTI		
Stocrin (EFZ)	36.0	20.58
Viramune (NVP)	19.5	11.15
PI		
Norvir (RTV)	9.4	5.37
Crixivan (IDV)	3.7	2.12
Kaletra (LPV/r)	1.5	0.86
Total market	174.9	100

Source: IMS

Table 7: Market Shares: NRTI Antiretrovirals (12 Months Ending June 2003)

Drug	Revenue (Million Rand)	Percent of total revenues
Combivir (3TC + AZT)	61.8	58.97
Videx (ddI)	18.2	17.37
3TC (3TC)	11.7	11.16
Retrovir (AZT)	8.3	7.92
Zerit (d4T)	4.8	4.58
Total NRTI market	104.8	100

Source: IMS

Table 8: Market Shares: NNRTI Antiretrovirals (12 Months Ending June 2003)

Drug	Revenue (Million Rand)	Percent of total revenues
Stocrin	36.0	64.86
Viramune	19.5	35.14
Total NNRTI market	55.5	100

Source: IMS

[REDACTED]

⁴⁵⁴ Market share data from IMS.

5.1.3 Market Power

The purpose of undertaking the market definition exercise and establishing market share is to substitute a proxy for the determination of whether a firm has market power.⁴⁵⁵ However, the need to define the market can be obviated if it is possible to establish the presence or absence of market power. In this case, GSK and BI each control patents that enable them to block generic competition for AZT, 3TC, Combivir and NVP. That provides presumptive evidence of market power.

While competition within a therapeutic class or subclass may constrain the pricing power of other firms in the class, it is generally not sufficient to prevent them from exercising market power. Even with competition within the therapeutic class, firms are able to charge supracompetitive prices, almost always considerably more than 5-10 percent more than the competitive price, the threshold under most international competition rules to establish market power.

There is substantial evidence that the respondents have market power with respect to each of their ARV products. As Table 9 and Table 10 show, the respondents' private sector prices are 1.3 to 7.3 times higher than the best price the companies offer to the government, and 5.2 to 14.1 times higher than best world price for the products, not including VAT and other costs of distribution. The firms are thus charging considerably more than 5-10 percent above the competitive price, establishing that they wield market power.

Pricing of the respondents' products is not constrained by new entrants into the market. In the last two years, pricing of HIV/AIDS products in South Africa has fallen significantly, because a) international publicity has been focused on the pharmaceutical industry's pricing practices for HIV/AIDS drugs; and b) international generic firms have made available generic versions of HIV/AIDS drugs at a tiny fraction of the prices previously charged by the patent holders, raising public awareness of the high prices being charged in poor countries relative to cost factors. These facts, external to the South African market, make it difficult to examine the impact of new entrants into the South African market.

An analysis of prices in the US State of Maryland, which has not been affected by these external factors, shows that prices for all ARVs have steadily risen as new products have entered the market.⁴⁵⁶ If the products competed effectively with one another, competition among 14 products in the HIV/AIDS market should lower prices; so should competition among 6 products in the NRTI market (with the key products controlled by two firms); and among the two products in the NNRTI market. But prices have in fact risen for each medicine, even in the periods directly after a new competitor entered the market.⁴⁵⁷ This is very strong evidence that each of the firms selling each of the products has market power.⁴⁵⁸

⁴⁵⁵ "[F]inding the relevant [product] market and its structure is not a goal in itself but a surrogate for market power," explains the leading US antitrust treatise. Areeda et al., IIA *Antitrust Law* ¶ 531a (1995).

⁴⁵⁶ See James Love and Thiru Balasubramaniam Expert Report, *Price Evolution of Antiretroviral Drugs 1996 to 2002; Maryland Reimbursements for Medicaid Program* (Expert Report JL/TB(B)).

⁴⁵⁷ In the NNRTI market, the daily dosage of NVP started at \$7.68 in Maryland in the fourth quarter of 1996. By the second quarter of 1999, it had risen to \$8.20. At this point, EFZ entered the market. The EFZ price for Maryland started at \$12.18 for a daily dose and rose to \$12.99 by the end of 2002. The price of NVP continued to rise after a viable competitor entered the market. It rose steadily, rising in every quarter except one, to close

Table 9: [REDACTED]

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Table 10: [REDACTED]

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5.2 ESSENTIAL FACILITIES

All of the elements of a violation of the essential facilities doctrine, as described by the Competition Appeal Court in *Glaxo v. National Association of Pharmaceutical Wholesalers*, are met. Access to the respondents patents are necessary for competitors to reasonably provide competing ARV products to consumers in South Africa, including three-drug FDCs that the patent holders do not provide and that would significantly improve the ease of adherence to HAART. It is economically feasible for the respondents to provide access to their patents through open licensing on standard terms and at reasonable and nondiscriminatory royalties.

at \$10.28 at the end of 2002. Pfizer/Pharmacia's Delavirdine is viewed as an inferior product, though its price too has steadily risen since entering the market in the second quarter in 1997.

⁴⁵⁸ Given that the market participants are the same in both locations, there is no evident reason why the firms should have market power in Maryland but not in South Africa.

⁴⁵⁹ [REDACTED]

⁴⁶⁰ [REDACTED]

⁴⁶¹ [REDACTED]

⁴⁶² [REDACTED]

5.2.1 The Resource Cannot Reasonably be Duplicated

Patents that the respondents hold on AZT, 3TC and NVP meet the first element of essentiality. The respondents' patents cannot reasonably be duplicated because there is no legal alternative to a patent. The receipt of licences for the respondents' patents is a legal prerequisite for the creation of generic versions of the ARVs subject to the complaint, including generic FDCs such as the three-drug combinations that are only available from generic suppliers.⁴⁶³ The refusal of the respondents to issue licences for their patents does more than inflict "a severe handicap on potential market entrants."⁴⁶⁴ The denial of licences legally bans market entry.

5.2.2 Competitors Cannot Reasonably Provide Goods without Access

The patents that the respondents hold on AZT, 3TC and NVP also meet the second element of essentiality in that competitors cannot reasonably provide competing goods without access to them. Here, the focus is on whether there are other close actual or potential substitutes that competitors can produce without licences to the respondents' patents that can effectively compete with the patented products.

As the report explains more fully in the previous section, where a licence for intellectual property is needed to produce a medical product that will contribute to addressing important public health concerns, there are no effective substitutes in the relevant market if

- (1) existing medicines in the same therapeutic class are complements rather than substitutes for the product; or
- (2) the product is an improvement over other products in terms of cost or therapeutic benefits to some patients; or
- (3) public health authorities counsel that the specific medicine should be provided by the medical system to meet public health concerns.

In each of the above circumstances, competition between products will not perform normal competitive functions that benefit consumers because substitution will be adverse to public health and therefore will not occur to the same extent as when substitution is positive to consumer welfare.

In this case, all three factors are met. "Effective therapy requires commencement of three drugs simultaneously, and alternative regimens are necessary to meet specific requirements at start-up, to substitute for first-line regimens in the case of toxicity, or to replace failing regimens."⁴⁶⁵ For these reasons, ARVs in the same therapeutic class are complements rather than substitutes. This is similar to the situation that the ECJ found in *Istituito Chemioterapico Italiano and Commercial Solvents Corporation* [1974] ECR. 223 with regard to medicines needed to treat TB. As Advocate General Jacobs described in his opinion in the

⁴⁶³ On the legal barriers that the respondents' patents pose to the marketing of three-drug fixed dose combinations, see Expert report by Brook Baker; MSF letter to Competition Commission (July 2003).

⁴⁶⁴ *Hecht*, 570 F.2d at 992-93.

⁴⁶⁵ *12th Expert Committee on the Selection and Use of Essential Medicines Meeting, 15-19 April 2002*, Annexure F to Statement of Complaint.

Oscar Bronner case, “the court found that the active ingredient ethambutol was used in combination with other medicines used to treat TB and therefore other medicines in the same class were not effective substitutes for purposes of competition analysis.”⁴⁶⁶

For similar reasons, each ARV can be considered an improvement over other ARVs in the same class for some patients. In some cases, this may be due to cost. For example, it is far cheaper to produce d4T than many other drugs in its class because of the low amount of active ingredient required per dose. In many cases the improvement is therapeutic. For example, EFZ cannot be used with women of child-bearing age and, therefore, for these patients, only NVP can be used as the third drug in an NNRTI based regime. Each ARV has a different side effect profile and therefore for individual patients one ARV or another may be an important improvement over other possible members of the class.⁴⁶⁷

In the case of three-drug FDCs, there are no actual or potential substitutes because the patent holders have not cross licensed to each other and therefore there is no comparable three-drug FDC available from the respondents. In relation to three-drug FDCs, this case presents a strong parallel to the *Magill* case in which the ECJ found that there was “no actual or potential substitute” for the complainant’s combination TV guide where the failure of each broadcaster to licence its individual listing prevented “the appearance of a new product . . . which the appellants did not offer and for which there was a potential consumer demand.”⁴⁶⁸

Perhaps the most important factor prohibiting effective substitution arises because of the need to change regimes where treatment failure occurs. WHO treatment guidelines state that each country must have two complete HAART regimes available in order to accommodate regime changes in case of treatment failure. The second regime must be composed of an entirely new set of NRTI drugs for the backbone (e.g. switching from AZT+3TC to d4T+ddI) and a new third drug from a different class (e.g. switching from an NNRTI to a PI or ABC). Because there are only four widely used NRTI medicines, and because NVP is the only NNRTI choice for many patients,⁴⁶⁹ “[t]he unavailability of either [AZT], [3TC] or [NVP], removes the possibility of constructing two three-drug regimens for the majority of those who require them.”⁴⁷⁰ In other words, each ARV that is subject to this complaint is a non-replaceable component for the establishment of an effective treatment programme in South Africa.

For all of the above reasons, the WHO and all of the medical experts who have submitted opinions in this case recommend that AZT and 3TC and NVP be available for treatment needs regardless of the availability of other ARVs within or between the various classes. The

⁴⁶⁶ Opinion of Mr Advocate General Jacobs delivered on 28 May 1998, *Oscar Bronner GmbH & Co. KG v Mediaprint*, [1998] ECR I-7791, para 60.

⁴⁶⁷ See WHO, SCALING UP at 84-121 (describing the individual profiles for each ARV for patients depending on potential side effects, compatibility with other drugs, interaction with other medical conditions, etc.).

⁴⁶⁸ *Radio Telefis Eireann v Commission of the EC* [1995] ECR. I-743 at para 54.

⁴⁶⁹ See Expert Affidavit of Robin Wood, Annexure RW to Complaint para 25 (explaining that “the potential teratogenic effects of efavirenz preclude its use in pregnant women or women of childbearing age who are at risk of falling pregnant”).

⁴⁷⁰ Letter from Dr. Goemaere to the Competition Commission (July 2003). See also Expert Affidavit of Robin Wood, para 24 (explaining that AZT and 3TC are listed by the WHO “as the initial recommendation for the dual NRTI component” and that, if not used in the first line treatment regime, “AZT/lamivudine would then be required as potential components for second line regimens”); Expert Affidavit of Robin Wood, Annexure RW to Complaint para 25

medical experts agree that “ARVs, even within the same therapeutic class, cannot be considered as fully substitutable for each other.”⁴⁷¹

5.2.3 The Dominant Firms Refused to Give Access

The essential facility doctrine is designed to recognize the special cases where “a dominant undertaking must not merely refrain from anti-competitive action but must actively promote competition”.⁴⁷² The doctrine recognizes that “certain monopolies inherently give rise to a duty to deal fairly with competitors”; “Under this 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.”⁴⁷³ As Professor Reichman explains in his expert report submitted to the Commission: “In such cases, it is not conduct that violates the antitrust law so much as status, i.e., ownership and exercise of the facility in a way that damages competitors who rely upon it.”⁴⁷⁴

In this case, it is clear that the respondents have not actively promoted competition by instituting an open licensing programme such as that available under the ‘licences of right’ provisions of the Patent Act.⁴⁷⁵ [REDACTED]

[REDACTED]⁴⁷⁶ The result was that each respondent was able to extend and preserve significant market power.⁴⁷⁷

5.2.4 It is Economically Feasible to Provide Access

It is traditionally the burden of the respondent to present evidence showing that it is not economically feasible to grant access to an essential facility.⁴⁷⁸ A business justification defence is “valid if it relates directly or indirectly to the enhancement of consumer welfare”,

⁴⁷¹ Expert Affidavit of Robin Wood, Annexure RW to Complaint, para 43 (stating that due to “the matrix of interconnected factors relating to toxicity and effectiveness of treatment, access to a wide choice of ARVs is required in order to effectively administer HAART”); *see also* para 28 (“There is no single ARV regimen which will be ideal for either all patients or for all clinical situations. Therefore, it is necessary to have access to a combination of drug choices both within and between drug classes.”); *12th Expert Committee on the Selection and Use of Essential Medicines Meeting, 15-19 April 2002*, Annexure F to Statement of Complaint (explaining that ARVs are different than the case “where one essential drug may substitute easily for other members of a class”; “all drugs recommended should be included in the Model List”).

⁴⁷² *Advocate General’s opinion in Oscar Bronner* Para 34.

⁴⁷³ IP AND ANTITRUST, *supra* note 103, §13.3(c) (emphasis supplied).

⁴⁷⁴ Jerome Reichman Expert Report, *Compulsory Licences: History And Legal Principles* 31.

⁴⁷⁵ Section 53 of the Patent Act states that “the patentee may apply to the registrar for the patent to be endorsed with the words ‘licences of right’ and where such an application is made the registrar shall, if satisfied that the patentee is not precluded by contract from granting licences under the patent, cause the patent to be endorsed accordingly.”

⁴⁷⁶ *See* Section 7.3.1 below.

⁴⁷⁷ *Cf York Timbers* (explaining that a refusal to deal may violate competition law where it “extends, preserves, creates, or threatens to create significant market power in some market, which could be either the primary market in which the monopoly firm sells or a vertically related or even collateral market.”).

⁴⁷⁸ *See* James B. Kobak, Jr. *Antitrust Treatment Of Refusals To License Intellectual Property Unilateral Refusal To License Intellectual Property And The Antitrust Laws*, 658 PLI/Pat 603, 609 (2001) (“In the face of exclusionary conduct, the burden to show a valid business justification will rest on the defendant.”); *see Eastman Kodak Co.*, 504 US at 483-86; *Data General Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147, 1183 (1st Cir. 1994).

not to the mere enhancement of the economic welfare of the dominant firm.⁴⁷⁹ A mere loss of profits or other “self interest” in excluding competitors is not sufficient to render the granting of licences economically infeasible.⁴⁸⁰

The primary argument against mandating licences to intellectual property is that the reduction in profits that may follow may reduce incentives for future innovation.⁴⁸¹ As discussed more fully in the analysis of section 8(c) below, the low sales and average income in South Africa (and other developing countries) results in low incentives for the patent holders to produce innovative products for South African consumers and low actual spending on R&D for new innovative products. Thus, every expert report submitted in this case agrees that consumer welfare will be significantly enhanced by allowing lower cost generic medicine producers into the South African market over any possible negative impacts on global R&D investments.⁴⁸²

There is ample evidence that a royalty rate of two to eight percent of annual sales is a reasonable compensation term for pharmaceutical patent licences, and that royalties of approximately five percent are average for the industry.⁴⁸³ A much fuller description of how one may determine whether a royalty is reasonable relative to South Africa’s legitimate

⁴⁷⁹ *Data General Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147, 1183 (1st Cir. 1994); see also *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 US 585, 605 (1985) (“If a firm has been attempting to exclude rivals on some basis other than efficiency, it is fair to characterize its behavior as predatory.”)

⁴⁸⁰ See *Otter Tail v. United States*, 410 US 366, 380 (1973) (“The promotion of self-interest alone does not invoke the rule of reason to immunize otherwise illegal conduct.”); see also *United Brands and Commission of the EC* [1978] ECR. 207 at paras 177, 190-91 (rejecting the justification that a refusal to deal was in the dominant firm’s “own interest and that of competition” because it had “no option but to fight back or else disappear from this national market”).

⁴⁸¹ But see Jerome Reichman Expert report at 33 (“Whatever the merits of these arguments in developed economies, a case might logically be made for greater use of this doctrine in developing countries”).

⁴⁸² See Expert Reports by Professors Jack, Scherer, Hollis and James Love; see also F.M. Scherer, *Global Welfare in Pharmaceutical Patent Policy* (January 2003).

⁴⁸³ See F. M. Scherer (describing royalty rates in the US), and James Love, *Setting Reasonable Royalties for Nonvoluntary Licences* (Appendix). The Japanese Patent Office royalty guidelines that range from 0-6%. The average pharmaceutical industry royalty in the United States was 4.9 percent in 1999, according to the US Internal Revenue Service. According to a 1999 survey by Rose Ann Dabek, more than half of the surveyed cases, in-licensed pharmaceutical patents bore royalties of 5 percent or less. The German royalty guidelines are 2 to 10 per cent for pharmaceutical products. Bristol Myers Squibb licensed the patent on ddI for a 5 percent royalty, and the patent on d4T for single digits. The University of Minnesota recently licensed patents on Abacavir at a sliding scale of 5 to 10 percent. According to a February 2000 submission to the United States Trade Representative (USTR) by the US trade group PhRMA, five percent is the “average pharmaceutical royalty rate.” PhRMA’s submission is consistent with the recent presentation by Q. Todd Dickenson, former Director of the US Patent and Trademark Office and Undersecretary of Commerce, at the October 2002 meeting of the Trans Atlantic Consumer Dialogue’s Committee on Intellectual Property. According to Mr. Dickenson, a royalty payment of “about 4% . . . is a very standard royalty across all industries. Most royalties run between two and five percent.” The United Nations Development Programme, in its 2001 Human Development Report (108), noted that Canada’s compulsory licensing scheme for pharmaceutical products “used to pay royalties of 4%” and recommended that “Developing countries could award an extra 1-2% for products of particular therapeutic value and 1-2% less when R&D has been partially covered by public funds.” The license of right recently announced by Pharmacia Corp. for delavirdine (aka Rescriptor) is based on a 5% royalty standard. During the 1980s, Singapore routinely granted compulsory licenses for government use of patented pharmaceuticals with a 5% cap on royalties. In 1997, the Philippines Supreme Court approved a compulsory license for the cimetidine patents with compensation of 2.5 percent of the generic sale price. Other cases have used much higher royalty rates. The UK, for example, habitually awarded rates in excess of 20% and the result, according to F.M. Scherer, was a limited benefit to consumers.

contribution to global R&D is included in an expert report by James Love.⁴⁸⁴ At bottom, that analysis shows that it is always economically feasible to compensate a patent holder for a needed medicine through a royalty payment rather than by allowing the company free reign to set prices in the private sector beyond the means of the majority of population.

5.3 EXCLUSIONARY ACT

The respondents have impeded generic suppliers from entering into the South African market for ARV products by refusing to grant licences for their patents to [REDACTED] [REDACTED]. The substantial anticompetitive effects of these acts outweigh the technological, efficiency or other pro-competitive gain that may flow from allowing the respondents to exclude competition in South African ARV markets.

5.3.1 Impediments to Entering or Expanding within a Market

[REDACTED] As we discussed in the previous section, it is appropriate to presume an unwillingness to grant a licence when a request is not granted within a reasonable time. [REDACTED]

[REDACTED]

485

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁴⁸⁴ See James Love, *Compensation for Non-Voluntary Use of a Patent* (Expert Report JL(A)).

⁴⁸⁵ [REDACTED]

[REDACTED]

[REDACTED]

486

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

487

[REDACTED]

⁴⁸⁶ [REDACTED]
⁴⁸⁷ [REDACTED]

5.3.2 The Anti-Competitive Effects Outweigh Any Pro-Competitive Gain

All of the ARV products at issue in this case are necessary to meet the recognised public health concern posed by the AIDS epidemic. HAART is not being accessed by hundreds of thousands of people in South Africa who need it to survive. Part of the reason for the widespread lack of access to needed medicines is that the respondents' refusals to grant licences for their patents has maintained prices at multiple times above the competitive level and inhibited three-drug FDCs from entering the South African market. Under these circumstances, it can be conclusively presumed that the whatever incentives are created to produce additional medicines that will benefit South African consumers in the future cannot outweigh the social costs of lack of access to medicines now. This conclusion is substantiated by a review of the available evidence.

5.3.2.1 Anticompetitive Effects

Lack of access to affordable medications because of refusals to licence patents can be traced to a number of devastating effects.

Harm to Competition. The harm to competitors and the competitive process in this case is plain. There are no competitors for the ARVs supplied by the respondents in the private market and only one potential competitor – Aspen Pharmaceuticals – in the public market. At least one specific competitor that is ready and willing to supply products in South Africa – [REDACTED]. There are many other international suppliers of generic ARVs that one can assume would enter the South African market under open licensing of the respondents' patents.⁴⁸⁸

It is well established that competition laws protect the competitive process in order to safeguard the welfare of consumers, not that of any particular competitor. In this case, the anticompetitive effect of the refusals of the respondents to licence their patents is significantly higher prices for consumers⁴⁸⁹ and lack of access to downstream innovations in the form of three-drug FDCs that are not provided by the respondents and for which there is a potential consumer demand.

Decreased household affordability. If prices in the private sector are reduced through competition, then more individual households would be able to afford HAART from a reasonable proportion of their income. [REDACTED]

[REDACTED]

Assuming that households cannot afford to spend more than 5% of their income on medicines,⁴⁹⁰ an average earner in the top 20% income bracket will have no more than

⁴⁸⁸ See MSF letter to Competition Commission (July 2003); MSF, *Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries* (May 2003).

⁴⁸⁹ See Reiffen, David and Michael Ward, *Generic Drug Industry Dynamics*, Federal Trade Commission (February 2002), available at www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf (finding that “the negative effect of increased competition on prices continues until at least the fifth, and perhaps even the sixth or seventh firm enters” a market and “the extent to which prices approach competitive levels in a market depends upon, among other things, the potential revenues in the market.”).

⁴⁹⁰ See Income and Expenditure Survey (IES) 2000, Statistics South Africa, available at www.statssa.gov.za; Integrated Household Survey 1993, World Bank, available at

R3,000 a year to spend on medicines.⁴⁹¹ This may be sufficient to purchase the least expensive generic HAART regime on the world market (R1,535 not including VAT and other mark ups), but not the branded products from the respondents. At competitive prices with reasonable royalties paid to the patent holders, more people would be able to access ARVs through a reasonable proportion of their household budgets, leaving income for other uses and relieving the burden on the state and society.

[REDACTED]

[REDACTED]

492

[REDACTED]

[REDACTED]

Decreased national affordability. The anticompetitive effect of the respondents' failure to licence competition in South Africa extends to the public sector. First, licensing would decrease the number of people who need treatment through the public sector as more people would be able to afford treatment on their own, including through their private health insurance. This would lessen the burden of the state, enabling it to focus its resources elsewhere.

www.worldbank.org/html/prdph/lsmc/country/za94/za94data.html#top (concluding that white households spend between 3-5% of their income on out of pocket medical expenses); *see also* Thomas J. Songer, Ronald E. LaPorte, Judith R. Lave, Janice S. Dorman and Dorothy J. Becker, *Health Insurance and the Financial Impact of IDDM in Families with an IDDM-affected Child* (undated study funded by National Institutes of Health) (finding that median out of pocket expenditure on health care in the US, including insurance premiums, totals 5% of household income); 42 CFR § 457.560 (requirement that states cap out of pocket contributions to health care at 5% of family income to participate in the Child Health Insurance Program).

⁴⁹¹ This assumption ignore the social fact that households will likely have other health care costs and may very well have more than one person in the household with in need of HAART or another expensive medicine.

⁴⁹² [REDACTED]

Second, open licensing would allow competitive suppliers to enter the market allowing the state access to the same supply of high quality generic products available to the private sector. Although exact figures are not available, one can estimate the impact of price decreases on the ability of the government to provide medicines to all who are in immediate need. The following table assumes a budget of R2.2 billion for treatment and that 80% of the treatment costs will arise from the cost of drugs.⁴⁹³

Table 11: Purchase Price Implications at Fixed Budget: R2.2 billion⁴⁹⁴

Cost of acquisition of ARV medicines (US \$)	Number of people potentially treated with R2.2 billion (80% medicine costs)
\$1200 ⁴⁹⁵	195,555
\$700 ⁴⁹⁶	335,238
\$300 ⁴⁹⁷	782,222
\$200 ⁴⁹⁸	1,173,333

If one assumes, based on all the above factors, that licensing generic suppliers would lead to 20% of patients with AIDS being able to obtain treatment in the private sector, and that these individuals would not have previously been able to obtain treatment, the government's estimates indicate that the benefit would include 293,269 deaths deferred, 5.2 million years of life gained and 140,000 orphans deferred by 2010.⁴⁹⁹

Social and economic effects. Lack of access to medicines has been linked to a number of social and economic effects that negatively spiral in interrelated patterns of causation.⁵⁰⁰ Death of members of society has enormous social costs. The precise number of deaths that would be averted in any given year from increased access to HAART that would accompany increased affordability and availability of easier to administer fixed dose formats is difficult to estimate, in part because price and lack of access to innovative formats are not the only

⁴⁹³ See www.globalfundatm.org

⁴⁹⁴ Table by Achal Prabhala, Yale School of Management.

⁴⁹⁵ Roughly the current cost of the lowest priced three-drug cocktail from the respondents (AZT+3TC+NVP).

⁴⁹⁶ The approximate cost of the lowest public sector price for a three-drug treatment from the respondents. See MSF, *Untangling the web of price reductions* (4th ed. May 2003).

⁴⁹⁷ The approximate price of the least expensive three-drug HAART regime approved by the WHO Pilot Procurement, Quality and Sourcing Project. See MSF, *Untangling the web of price reductions* (4th ed. May 2003).

⁴⁹⁸ Roughly the cost of current least expensive three-drug fixed dose combination on the world market (d4T+3TC+NVP), see MSF, *Untangling the web of price reductions* (4th ed. May 2003). One may predict that an overall treatment program could average the cost of medicine at about \$200/yr per patient, including higher priced second line treatments for those who need them, if full competition in South Africa and other developing countries led to economies of scale that prompted suppliers to reduce the price of the cheapest first line treatment to under \$100 /yr, as many predict. See James Love and Thiru Balasubramaniam, *The Effects of Generic Competition on Drug Prices Over Time* (Expert Report JL/TB(A)); MSF letter to Competition Commission (July 2003) (describing estimate of the marginal costs of drug production).

⁴⁹⁹ *Summary Report of the Joint Health and Treasury Task Team Charged with Examining Treatment Options to Supplement Comprehensive Care for HIV/AIDS in the Public Sector* 18 (1 August 2003).

⁵⁰⁰ See Iris Boutros Expert Report, *The Socio-Economic And Demographic Impact Of The Hiv/Aids Epidemic In South Africa* ("Communities, households, and individuals in South Africa experience the impact of the HIV epidemic in a variety of aspects of life. The most obvious are the direct effects to health and life. Direct and indirect consequences of ill health include things like compromises to labour productivity and income. Equally important is the impact of the HIV epidemic on population size and structure.").

barriers to treatment.⁵⁰¹ Economic models exist for estimating the value of an adult life to society, but we did not apply any such model in our analysis.⁵⁰²

Some of the documented social and economic effects of lack of access to ARVs in individual households include:

- Decreased household incomes;⁵⁰³
- Increased infection of others;⁵⁰⁴
- Deepening hunger related to inability of rural people to grow food and fetch water;⁵⁰⁵
- Ultimately, increased poverty in all of its social dimensions.⁵⁰⁶

On a national level, lack of treatment for AIDS results in:

- Decreased average life expectancy;⁵⁰⁷
- Increased costs to the health care system from hospitalization and treatment of opportunistic infections;⁵⁰⁸

⁵⁰¹ See WHO Regional Office of the Western Pacific, 8 *HIV/AIDS Antiretroviral Newsletter* (December 2002) (“Access to medicines depends on many factors, notably rational selection and use of drugs, adequate and sustainable financing, affordable prices, and reliable supply systems.”).

⁵⁰² See Dean Jamison, Jeffrey Sachs and Jia Wang, *The Effect of the AIDS Epidemic on Economic Welfare in Sub-Saharan Africa*, Commission on Macroeconomics and Health Paper No. WG1: 13, 4-5 (December 2001) (reviewing literature finding that societies’ willingness to pay to avert an adult death range from 75 to 180 times GDP per person and “conservatively” assuming the value of averting an adult death to be 100 times GDP per capita).

⁵⁰³ Duncan Thomas and John Strauss, *Health and Wages: Evidence on Men and Women in Urban Brazil*, *Journal of Econometrics*, 1997, 77, pp. 159-185.

⁵⁰⁴ Sally Blower and Paul Farmer, *Predicting the Public Health Impact of Antiretrovirals: Preventing HIV in Developing Countries*, *AIDS Science*, 2003, 3(11); Moatti, Jean Paul et al., *The evaluation of the HIV/AIDS Drug Access Initiative in Cote D’Ivoire, Senegal and Uganda: How Access to Antiretroviral Treatment Can Become Feasible in Africa*, *AIDS*, 2003, 17(3) (concluding from a study conducted in Ivory Coast in 2000 that ARV-treated HIV infected people are more likely to have one main partner, more likely to disclose their HIV status to their partner and their families, and more likely to use condoms frequently, as compared to non-treated HIV+ people).

⁵⁰⁵ Stephen Lewis, Speech to the Global Health Council’s Annual Conference (28 May 2003) (reporting on trip to Southern Africa with James Morris, Executive director of the World Food Program).

⁵⁰⁶ See United Nations Population Fund, *STATE OF THE WORLD POPULATION 2002: PEOPLE, POVERTY AND POSSIBILITIES 10* (2002) (“HIV/AIDS accompanies poverty, is spread by poverty and produces poverty in its turn.”); *id.* at 43 (“Individuals, households and communities living with HIV/AIDS find that lost earnings, lost crops and missing treatment make them weaker, make their poverty deeper and push the vulnerable into poverty. The cycle intensifies.”).

⁵⁰⁷ See SOUTH AFRICA 1999/2000 SURVEY 1 (“The United States Census Bureau in 1998 revised its estimate of the average life expectancy in South Africa from 65 to 56 because of AIDS. The population growth rate estimate was also revised from 1.9% to 1.4%.”).

⁵⁰⁸ See Ministry of Health, National HIV-AIDS Program, Brasilia, Brazil: Ministry of Health (2003) available at <http://www.aids.gov.br/final/biblioteca/drug/drug7.htm> (reporting on health care system savings from providing HAART); United Nations Population Fund, *STATE OF THE WORLD POPULATION 2002: PEOPLE, POVERTY AND POSSIBILITIES 44* (2002) (reporting that HIV/AIDS increasingly “overwhelmed” health care systems in Africa in the 1990s and “[t]he result was to deprive many Africans of any health care at all”).

- Increased “dependency burden” represented by the proportion of the population too young or too old to provide for themselves and others;⁵⁰⁹
- Lower productive capacity per capita and lower rates of saving and investment;⁵¹⁰
- Decreased lifetime earnings and rates of return to education;⁵¹¹
- Ultimately, decreased growth in gross domestic product⁵¹² and economic welfare⁵¹³ and the possibility of “complete economic collapse”.⁵¹⁴

5.3.2.2 Technological, Efficiency or Other Pro-competitive Gains from Refusing to Deal

The primary technological, efficiency or other pro-competitive gain from allowing a patent holder the power to exclude all competition from the relevant market is as “an imperfect incentive for innovators first to innovate and second to disclose their innovation”.⁵¹⁵ It is, therefore necessary to analyse the benefits that South African consumers receive from the respondents’ investments in new product innovation.

Incentives to innovate. The UK Commission on Intellectual Property Rights concluded that patent protection “hardly plays any role at all” in stimulating development of treatments for developing countries “except for those diseases where there is a large market in the developed world” and therefore would have been developed in any case. The report

⁵⁰⁹ United Nations Population Fund, STATE OF THE WORLD POPULATION 2002: PEOPLE, POVERTY AND POSSIBILITIES 16 (2002); *id.* at 12 (“The HIV/AIDS pandemic may close the demographic window before it opens, because the death of young adults stunts the growth of the working-age population. The disease both devastates the present and steals the future.”); *see also* David Bloom et al., THE DEMOGRAPHIC DIVIDEND: A NEW PERSPECTIVE ON THE ECONOMIC CONSEQUENCES OF POPULATION CHANGE (2002).

⁵¹⁰ David Bloom & Jeffrey Sachs *Geography, Demography, and Economic Growth in Africa*, 2 BROOKINGS PAPERS ON ECONOMIC ACTIVITY 207 (1998).

⁵¹¹ Dean Jamison, Jeffrey Sachs and Jia Wang, *The Effect of the AIDS Epidemic on Economic Welfare in Sub-Saharan Africa*, Commission on Macroeconomics and Health Paper No. WG1: 13, 12 (December 2001) (reporting an absolute drop of 2% in the private rate of return

⁵¹² *See* David Bloom & David Canning, *The Health and Wealth of Nations*, SCIENCE 1207 (1999) (reporting that a country with 5-year higher life expectancy will grow 0,3 to 0,5 percent per year faster, all else being equal); Dean Jamison, Jeffrey Sachs and Jia Wang, *The Effect of the AIDS Epidemic on Economic Welfare in Sub-Saharan Africa*, Commission on Macroeconomics and Health Paper No. WG1: 13, 3 (December 2001) (estimating “that the impact of increase in adult male mortality rates between 1999 and 2000 would result in a drop of a very substantial 0.5% per annum in the growth rate of GDP per capita in Africa” but that “[t]his underestimates the impact of the AIDS epidemic since, virtually certainly, the adult mortality for Africa would have declined absent the epidemic”).

⁵¹³ Dean Jamison, Jeffrey Sachs and Jia Wang, *The Effect of the AIDS Epidemic on Economic Welfare in Sub-Saharan Africa*, Commission on Macroeconomics and Health Paper No. WG1: 13 (December 2001) (estimating -2.6% growth in welfare in sub-Saharan Africa due to the AIDS epidemic, using measurement of welfare based on what societies appear willing to pay to reduce death rates).

⁵¹⁴ Clive Bell, Shantayanan Devarajan and Hans Gersback, *The Long-run Economic Costs of AIDS: Theory and an Application to South Africa* World Bank (March 2003) (estimating much higher impacts on GDP from lack of treatment than previous studies, including the possibility of “complete economic collapse” in South Africa, because “[n]ot only does AIDS destroy human capital, but by killing mostly young adults, it also weakens the mechanism through which knowledge and abilities are transformed from one generation to the next”).

⁵¹⁵ Hollis expert report.

concluded that “presence or absence of IP protection in developing countries is of at best secondary importance in generating incentives for research directed to diseases prevalent in developing countries.”⁵¹⁶

The expert submissions in this case are in accord. Professor William Jack concludes that “that any reduction in profits from South African sales [at low royalty rates] (which would, in any case, be limited due to a resulting expansion in sales volume) would not have a significant effect on world-wide firm profits, and thus would be unlikely to deter future R&D investment for drugs with global markets.” On a similar note, Professor Hollis explains that “while there may be some reduction in profits from compulsory licensing, it may be relatively small compared to the huge benefits created for very poor people.”

For these reasons, both Professor Jack and Professor Hollis recommend that the Competition Act be interpreted to authorise compulsory licences whenever the price of needed medicines is higher than a competitive market would produce and the result is a significant number of people who cannot afford treatment. “In such cases,” explains Professor Hollis, “it can be confidently and conclusively presumed that ‘the anti-competitive effect’ of the failure to licence all qualified suppliers – the deadweight loss represented by South Africans who will die from AIDS that otherwise would have lived – far outweighs the ‘technological, efficiency or other pro-competitive gain’ to consumers in terms of future innovation incentives from the maintenance of monopoly pricing power.”⁵¹⁷

It is noteworthy that the Canadian Royal Commission of Inquiry on the Pharmaceutical Industry (referred to as the “Eastman Commission”) concluded that Canada’s mandatory compulsory licence scheme for medicines did not adversely affect the research-based Canadian pharmaceutical industry or the R&D decisions of the multinational pharmaceutical industry and that the program saved Canadian consumers \$200 million in 1983 alone.⁵¹⁸

Actual contributions to R&D. The respondents’ actual contributions to R&D out of sales in South Africa is comparatively small.⁵¹⁹ GSK’s most recent annual report claims 15.2 percent of turnover is invested in R&D. BI claims global R&D on “innovative new medicines” equal 17.2 percent of global sales.

There is considerable evidence that a significant amount of reported R&D is devoted to studies that are designed to achieve marketing purposes, or are invested in products that are

⁵¹⁶ UK Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* 32-33 (2002) (the Commission added: “Regardless of the intellectual property regime prevailing in developing countries, in reality there is little commercial incentive for the private sector to undertake research of specific relevance to the majority of poor people living in low income countries”).

⁵¹⁷ See also F. M. Scherer, *Global Welfare in Pharmaceutical Patent Policy* (2003) (concluding from an economic analysis that, even with no royalties paid to the patent holder, “global welfare is maximized by letting low-income nations free-ride on the patented inventions of first-world nations over a wide range of negative new product development impacts if one accepts the reasonable premise that the marginal utility of income is appreciably higher in poor nations than rich nations”).

⁵¹⁸ *The Canadian Experience* at 38. The report suggested granting only four years of exclusive patent protection for pharmaceutical products (without compulsory licensing in those years) following which compulsory licensing would proceed as of right at a higher royalty rate than the traditional four percent for companies that engaged in R&D in Canada.

⁵¹⁹ See James Love Expert Report Love, *Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines* (Expert Report JL(C)).

no better than products already on the market. According to the Pharmaceutical Research and Manufacturer Association’s 2002 annual membership survey, 71 percent of reported R&D expenditure is devoted to the development of new medicines, including pre-clinical, clinical research through approvals, and regulatory approval costs. According to the Tufts University analysis [REDACTED] 74 percent of R&D outlays are devoted to the discovery and approval of a product, and 26 percent of outlays are associated with studies of older products, many of them studies comparing products for marketing purposes.

Most of the investment actually devoted to new products by multinational pharmaceutical companies is invested in products that are no better than existing medicines. According to the US Food and Drug Administration, over the past ten years, only 31 percent of new molecular drugs are rated as priority products that are significantly better than existing medicines. The FDA also reports that non-innovative products (for which the standard approval system applies) require larger clinical trials.⁵²⁰

Assuming that 75 percent of R&D funding is invested in new products, and 20 percent of that is invested in priority products, the investment in new products that are significantly better than existing medicines would be only 2.3 percent of sales for GSK and 2.6 percent of sales for BI.

Table 12: GSK and BI global rates of investment in R&D⁵²¹

	Self Reported global rate of investment in R&D	Investment in older products	Investments in new products that are not significantly better than existing treatments	Investments in new products that are not significantly better than existing treatments
GSK	15.2%	3.8%	9.1%	2.3%
BI	17.2%	4.3%	10.3%	2.6%

Table 13: Benefits in R&D funded by current sales of GSK and BI antiretroviral products⁵²² (Millions of Rand)

	Sales in ZAR through June 30, 2003	R&D invested in older products	R&D invested in products not significantly better than existing treatments	R&D invested in new significantly better products	Total
GSK	R81.8	R3.1	R9.3	R1.9	R14.3
BI	R19.5	R0.8	R2.5	R0.5	R3.9

Alternative mechanisms for investment in R&D. Finally, it is important to note that the death and morbidity that results from unaffordable prices of needed medicines is not offset by a benefit that cannot be garnered through other means. A contribution to the respondents’ research and investment can be made through a royalty payment. Any additional socially beneficial investment in R&D can be targeted by South Africa through mechanisms – such as

⁵²⁰ The average size of trials for the median standard approvals is 1.8 times higher than the average clinical trial size for the priority approvals. For the median, the ratio is 2.5.

⁵²¹ Data and table by James Love.

⁵²² Data and table by James Love.

direct government funding – that have a much less drastic effect on the health and welfare of the nation and can be targeted to South Africa’s particular needs.

5.4 CONCLUSION

For the above reasons, we conclude that the respondents have refused to grant licences for their patents on reasonable terms and that the effect of these refusals has been to (a) deny competitors access to essential facilities where it is economically feasible to grant access in violation of Section 8(b) of the Act, and (b) exclude competitors from the relevant market where the anticompetitive effect of the exclusion outweighs its technological, efficiency or other pro-competitive gain in violation of section 8(c) of the Act.

SECTION 6: REMEDY

Section 58 of the Competition Act empowers the Tribunal to make any “appropriate order in relation to a prohibited practice,” including “ordering a party to supply or distribute goods or services to another party on terms reasonably required to end a prohibited practice” and “ordering access to an essential facility on terms reasonably required.” In this case, the “appropriate order” is a compulsory open licence that would authorize third parties to exploit the patents needed to manufacture ARV products.

Compulsory licenses are more effective at correcting market failures caused by monopoly pricing than price controls because they introduce the dynamic effects of competition to lower prices over time.⁵²³ A compulsory licensing remedy is also the only remedy that will permit new entrants to create new fixed dose combinations and other product innovations that address the needs of HIV patients.

The issuance of compulsory licenses as a remedy for anticompetitive practices is clearly contemplated in both TRIPS and the Doha Declaration as a key “flexibility” needed to promote access to medicines. Compulsory licences have been frequently used by many countries, including the US, those with the EC, Canada, the UK, Germany, New Zealand, Japan, the Philippines and Singapore, in cases involving abuses of patent rights or violations of competition laws.⁵²⁴

6.1 TERMS OF A COMPULSORY LICENCE

As part of its request of an appropriate order from the Tribunal, we recommend that the Commission pursue an order that authorises any person to exploit the patents to manufacture generic versions of their patented medications or FDCs that require these patents, in return for payment of a reasonable royalty to the patent owner. The following terms should apply:

- (a) The authorization should include the right to import, export, make, offer for sale, sell or use the product.⁵²⁵
- (b) The reasonable royalty should be based upon the royalty guidelines set out below and explained in expert report by James Love, and should consist entirely of payments based upon a percentage of net sales of the generic competitor.
 - (i) In general, where there are multiple patents on a product, royalties will be divided equitably among the patents owners. The division of the royalties among patent owners can be by any method agreed upon by the patent owners, including an equal share for each patent, or by mutual agreement upon the appropriate "value," "utilization" or "increase/decrease" factor for each

⁵²³ See James Love Expert Report, *The Effects of Generic Competition on Drug Prices over Time* (appendix).

⁵²⁴ See Reichman expert report.

⁵²⁵ The right to export the product is essential if a domestic manufacturer seeks to achieve the necessary economies of scale to manufacture medicines most efficiently, and the availability of low cost generic products in export markets will contribute to economic development and better health care for the region. The right to export products under a compulsory license is specifically authorized under 31.k of the TRIPS accord.

individual patent, or in the absence of agreement, according to the outcome of arbitration between the patent owners.

- (ii) For patents associated with AZT, 3TC, AZT+3TC and NVP, the recommended royalty payments to GSK and BI for their combined patents are presented below for three standalone products, one two drug FDC, and two-three-drug FDCs.
 - (iii) any party exploiting the patented invention should be required to pay to the patent holder, on quarterly basis, with royalty payments due 30 days after the end of each period.⁵²⁶
 - (iv) If products are exported to a market where the products are subject to another compulsory license, the foreign royalty payments are to be credited against the royalties normally associated with the export sales.
- (c) the duration of the license should be for the term of the patent; unless the patent owner can demonstrate a shorter term would not prejudice the interests of consumers of medicines.

6.2 MONETARY PENALTY

The harm to consumers has been severe; life saving medicines have been priced excessively at a time when the suffering of patients is well known to both defendants. The monetary penalty should be the full 10 percent of annual turnover for each year that the respondents marketed their ARVs in South Africa in violation of the Competition Act.

6.3 ROYALTY GUIDELINES

The following proposed royalties are a modification of the UNDP and Japanese royalty guidelines. Both the UNDP and the Japan guidelines permit royalties from 0 to 6 percent. The modified guidelines permit royalties from 0 to 8.75 percent. Each product was assigned a base rate of 5 percent, the highest category (and a rate equal to the average pharmaceutical royalty in the US), and then adjustments were made based upon the utilization ratio and increase/decrease factors described in further detail in the attached report on setting a reasonable royalty. The royalty rates should be assessed as a percentage of the net sales of the generic products.

Table 14: Suggested Royalties for Standalone ARVs

	<i>Value</i>	<i>Utilization</i>	<i>Increase/ Decrease</i>	<i>Exploration</i>	<i>Total Royalty</i>
<i>Standalone</i>					
AZT	.05	100%	50%	100%	.025
3TC	.05	100%	100%	100%	.05
Nevirapine	.05	100%	150%	100%	.075

Source: James Love

⁵²⁶ 46.66, UK manual of patent practice.

Table 15: Suggested Royalties for AZT+3TC

<i>Fixed dose combination (AZT+3TC)</i>					
AZT+3TC	.05	10%	100%	100%	.005
AZT	.05	45%	50%	100%	.01125
3TC	.05	45%	100%	100%	.0225
Total					.03875

Source: James Love

Table 16: Suggested Royalties for AZT+3TC+NVP

<i>Fixed dose combination (AZT+3TC+NVP)</i>					
AZT+3TC	.05	10%	100%	100%	.005
AZT	.05	30%	50%	100%	.0075
3TC	.05	30%	100%	100%	.015
Nevirapine	.05	30%	150%	100%	.0225
Total					.05

Source: James Love

Table 17: Suggested Royalties for d4T+3TC+NVP

<i>Fixed dose combination (d4T+3TC+NVP)</i>					
D4T					
3TC	.05	30%	100%	100%	.015
Nevirapine	.05	30%	150%	100%	.0225
Total					.0375

Source: James Love

APPENDIX A: INDEX OF EXPERT REPORTS

Baker, Brook K. *Essential Facilities for Fixed-Dose Combination ARVs* (Expert Report BB)

Boutros, Iris. *The AIDS Epidemic in South Africa* (Expert Report IB(A))

Boutros, Iris. *Treatment and FDCs* (Expert Report IB(B))

Boutros, Iris. *The Socio-Economic and Demographic Impact of the HIV/AIDS Epidemic in South Africa* (Expert Report IB(C))

Correa, Carlos. *International Experience with Regard to “Refusal to Deal”* (Expert Report CC)

Fox, Eleanor M. *Section 8(A) Threshold for “Excessiveness” as Lower for Necessities than Luxuries* (Expert Report EF)

Flynn, Sean. *Focusing on Exclusionary Practices* (Expert Report SF)

Ghosh, Shubha. *Excessive Pricing As Abuse of Dominant Position* (Expert Report SG)

Hollis, Aidan. *Economic Analysis of the Need for a Compulsory License Remedy to Promote Access to Essential Medicines Under Section 8(c) of the South African Competition Act* (Expert Report AH)

Jack, William. *Economic Analysis of Prices and Royalties for ARVs in South Africa* (Expert Report WJ)

Lexchin, Joel. *The Role of Marketing in the Pharmaceutical Industry* (Expert Report JL)

Love, James. *Compensation for Non-Voluntary Use of a Patent* (Expert Report JL(A))

Love, James. *Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines* (Expert Report JL(B))

Love, James and Thiru Balasubramaniam. *The Effects of Generic Competition on Drug Prices Over Time* (Expert Report JL/TB(A))

Love, James and Thiru Balasubramaniam. *Price Evolution of Antiretroviral Drugs 1996 to 2002; Maryland Reimbursements for Medicaid Program* (Expert Report JL/TB(B))

Oxford Public Interest Lawyers, *EC Case Review Essential Facilities/Refusal to License* (Expert Report OXPIL(A))

Oxford Public Interest Lawyers, Sandra Fredman, *Relevance of the European Convention on Human Rights* (Expert Report OXPIL(B))

Palmedo, Mike. *Annex A – Antiretroviral Prices* (Expert Report MP)

Reichman, J. H. *Compulsory Licenses: History and Legal Principles* (Expert Report JHR)

Rovira, Juan. *Promoting Affordability of Antiretroviral Therapy (ART) in South Africa* (Expert Report JR)

Scherer, F.M. *In the Matter of Glaxosmithkline South Africa et al.* (Expert Report FMS)

Weissman, Robert. *The Legislative Purposes and History of the South Africa Competition Act* (Expert Report RW (A))

Weissman, Robert. *The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property* (Expert Report RW(B))

Weissman, Robert. *Economies of Scale are Important and a Compulsory License Must Permit Exports so that a Domestic Producer Can Reach Efficient Economies of Scale* (Expert Report RW(C))

Yamin, Alicia Ely. *Human Rights Obligations Regarding Access to Medications* (Expert Report AY)