Evaluation of Excessive Pricing

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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

LIST OF TABLES

ACRONYMS

3TC	Lamivudine, brand name Epivir
ABC	Abacavir, brand name Ziagen
AIDS	Acquired Immune Deficiency Syndrome
ARV	Antiretroviral Medicine
AZT	Zidovudine, brand name Retrovir
AZT+3TC	Zidovudine and Lamivudine, brand name Combivir
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
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
NVP	Nevirapine, brand name Viramune
PI	Protease Inhibitor
R&D	Research and Development
RSA	Republic of South Africa
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property
WHO	World Health Organisation
WTO	World Trade Organization

SECTION 1: INTRODUCTION

The complaint from Hazel Tau and others lodged before the Competition Commission alleges that GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI), and their South African subsidiaries, charges for zidovudine (AZT), lamivudine (3TC) and Combivir, and the price charged by BI for nevirapine (NVP) are excessive under Section 8(a) of the Competition Act. Because of global and domestic inequalities of income, the profit maximizing price for antiretroviral (ARV) products in South Africa are too high for most persons living with HIV to obtain access to treatment. The evaluation of the complaint is based upon a framework for considering excessive pricing. That framework divides goods into a matrix of essential, non-essential and luxury goods, which are in turn defined as intellectual property goods or physical goods and services. For essential intellectual property goods, a standard is presented where prices that are not affordable are presumed to be excessive, unless one of three conditions hold:

(a) The owner of the intellectual property has licensed the technology to competitors on a non-discriminatory basis (open licensing[1]) in return for a reasonable royalty, or

(b) If the competitive provision of the good is not economically feasible, the prices are reasonable in light of the cost of making the good available; or

(c) The given prices are necessary to generate the income needed for the development of the good, where there is no substantial market for the good in countries defined by the World Bank as high-income economies.

The patent owners had the opportunity to either price their medicines to be affordable to most people, or to license their patents to competitors in return for a reasonable royalty (permitting competition to lower prices and increase access). They have chosen instead to engage in restrictive licensing practices, and to set prices that only a tiny fraction of persons living with HIV could afford. We therefore conclude that excessive pricing has been established in this case.

[1] An open licensing programme is one in which all potential competitors are granted a licence on the same non-discriminatory terms, such as under the licences of right provisions of the Patent Act.

SECTION 2: THE ALLEGED VIOLATION

According to Section 8(a) of the South African Competition Act:

> It is prohibited for a dominant firm to -
>
> (a) charge an excessive price to the detriment of consumers;
>
> 'excessive price' means a price for a good or service which -
>
> > (aa) bears no reasonable relation to the economic value of that good or service; and
> >
> > (bb) is higher than the value referred to in subparagraph (aa);

GSK and BI are alleged to have violated the 8(a) by pricing medicines in a manner that "bears no reasonable relationship to the economic value of the good" to the detriment of consumers. The complainants include persons living with HIV who cannot afford the private sector prices for medicines that would treat a debilitating and eventually life ending disease. As outlined in the complaint, the prices charged by the GSK and BI in the private sector are far higher than the prices available from competitive suppliers in markets where GSK and BI do not have patents on their products. This is illustrated in Table 1. The private sector prices for the products in the complaint are *five to fifteen times* higher than the best global generic prices.

Table 1: Private Sector Prices as Percentages of Best Global Prices (Daily price in USD)

Drug	RSA private sector price to consumers (inclusive of VAT) on July 2003	Best global generic price (May 2003)	RSA private sector price as percent of best global generic price *(adjusted for VAT)*
GSK/AZT	2.94	.38	665%
GSK/3TC	3.23	.18	1,543%
GSK/Combivir	4.04	.56	620%
BI/NVP	1.82	.29	540%

Source: Michael Palmedo: Antiretroviral Prices

This evaluation considers the following question: Does a decision to price ARV products higher than are affordable to most persons living with HIV violate the Act?

SECTION 3: PROFIT MAXIMIZING PRICES IN SOUTH AFRICA

Firms may have a variety of motivations to price products at prices higher than are affordable for most residents in developing countries, including the fear that lower prices in one country will lead to demands for price reductions in other countries.[2] More troubling is the situation described in detail by Professor Hollis in his expert report,[3] and examined elsewhere by Scherer and Watal.[4] Pricing for a small elite will be the rational profit-maximizing price in countries with significant inequalities of income, when it is not feasible to price discriminate within a population. As noted by Scherer, favouring one demand segment consisting of an affluent minority with substantial per-capita income and comprehensive health insurance, at the expense of another for the less well-off and poorly-insured majority, approximates the conditions in South Africa, with its particularly unequal distribution of income.[5]

Using the available data on the distribution of income for South Africa by deciles, and assuming (as does Hollis) that for purposes of illustration the demand curve for medicines can be represented as a simple transformation of income distribution *(an assumption likely to underestimate the actual inequality in the ability to pay for medicines[6])*, the profit maximizing price would be one that was affordable by the top decile of the population. This is illustrated in Table 2. The affordable price is presented as the relative share of national income of each group. A firm could sell to only the highest income decile for a price of 45.16, or to the top two income deciles for a price of 17.73, and so on. The price affordable to all income deciles would be 1.08. Every time the firm lowers the price there is more access, but the fall in prices is always more important to the firm than the increased sales *(total revenue falls every time the firm lowers prices to expand sales)*, and the profit-maximizing price is the one that is only affordable to only a small fraction of the population. This is unfortunately not as stark as the actual outcome in South Africa, where less than 30 thousand out of 5 million persons living with HIV currently receive HAART treatment.

[REDACTED]

[2] Martin Adelman, "The role of patents in the quest for affordable access to drugs," Paper presented at Workshop on Key Issues in Improving the Accessibility to Drugs in Developing Countries, Session 3: Compensation and Compulsory Licenses: implementing the Doha Declaration and advancing the UN Millennium Development Goals, World Bank, June 2, 2003, Washington, DC.

[3] Expert Report, Professor Hollis.

[4] Jayashree Watal and F. M. Scherer, "The Economics of TRIPS Options for Access to Medicines," in Brigitte Granville, ed., The Economics of Essential Medicines (London: Royal Institute of International Affairs, 2002), pp. 42-48. As discussed by Scherer in his expert submission, "One hypothetical demand segment pertains to the affluent minority with substantial per-capita income and comprehensive health insurance; the other is the less well-off and poorly-insured majority. In this case there are two equilibria. If both consumer groups are served, we estimated a uniform profit-maximizing price of $24 per Rx, with 240,000 prescriptions filled monthly. But higher profits can be realized by catering only to the affluent minority at a price of $59 per Rx, with 102,500 prescriptions filled per month." The example presented by Scherer and Watal is contrived to show an equilibrium with fewer people receiving medicines, but it only hints at the outcomes that have actually occurred.

[5] Expert Report, Professor FM Scherer

[6] Wealth is more unequally distributed than income, and the poor have less access to capital markets, as well as pooling, insurance and financing mechanisms.

Table 2: Profit Maximizing Prices with Demand Curve Based Upon Income Distribution for 10 Income Deciles

Income Decile	Affordable Price	Total Sales as price falls to expand access *(Number of deciles multiplied by price)*	Change in Revenue as access is expanded *(marginal revenue)*
1	45.16	45.16	
2	17.73	35.46	-9.7
3	11.37	34.11	-1.35
4	7.82	31.28	-2.83
5	5.54	27.7	-3.58
6	4.1	24.6	-3.1
7	3.1	21.7	-2.9
8	2.36	18.88	-2.82
9	1.73	15.57	-3.31
10	1.08	10.08	-5.49

Professor Scherer discusses this dilemma in his expert submission as follows:

> Such a market segmentation strategy might have received a "distinction" grade in my marketing course at the Harvard Business School (to be sure, 45 years ago, before AIDS was known). But when the lives of thousands of persons are at stake, it is repugnant morally, and in my parallel "Business Responsibilities and Society" course, it might have received a "low pass" grade ("fail" grades being administered only rarely). Since competition policy was then (and apparently still is) the province of the "Business Responsibilities" course, it would not be inappropriate for a national competition policy authority to find evidence of such market segmentation strategies supporting a conclusion that a dominant market position has been abused.

SECTION 4: ESSENTIAL GOODS

For a variety of reasons, national *(or regional)* reactions to the issue of *excessive pricing* vary considerably. As described by Professor Eleanor Fox[7]:

> … enforcement of an excessive pricing law entails difficulties. First, one might fear that depriving a firm of the fruits of its success (monopoly prices) may undercut its incentives to become successful in the first place. Second, determining when a price is sufficiently excessive and at what level the price is not exploitative are difficult tasks. Thus, there are problems of incentives if "excessiveness" is found too freely, and there are problems of administrability. For these reasons, the United States does not have an excessive pricing prohibition. But in this regard the United States is not the model for the world.
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> The European Union provides the leading model for an excessive pricing prohibition. Under European Union law, a firm may abuse a dominant position by charging a price "which is excessive in relation to the economic value of the service provided . . . ." *General Motors Continental N.V. v. Commission*, 1975 ECR 1367. In *United Brands Company v. Commission*, 1978 ECR 207, the European Court of Justice laid down the framework for proof: One must "determine[] whether the difference between the costs actually incurred and the price actually charged is excessive, and if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products." para. 252. In *Sirena v. Eda*, 1971 ECR 69, the Court of Justice said that a high price of an intellectual property license may, "if unjustified by any objective criteria and if it is particularly high, be a determining factor" in finding an abuse of dominance.

Fox notes that pricing abuses that involve essential goods are appropriately considered under different standards than other goods.

> Because excessive pricing is inefficient, the prohibitory rule is justified even in nations that see efficiency as the core of the competition law. But excessive pricing is also unjust; excessive pricing of life-or-death necessities to the poor is particularly unjust; and under South African law justice and fairness share the platform with efficiency as legal bases. Applications of the South African Competition Law would appropriately take account of the distributional concerns found both in the Competition Law itself and in the Constitution of South Africa.
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> . . . the distinction between necessities and luxuries is eminently permissible if not compelled by South African law and its unique responsiveness to issues of distributional equity and fairness. The Commission could appropriately recognize a special mandate to protect poor people from excessive pricing of necessities of life. Such a mandate is not "robbing the rich" when the latter

[7] Expert Report, Professor Eleanor Fox

> are garnering so much more than a fair return at the expense of the sick; it is merely righting a balance; applying a principle of proportionality. When, as here, the interest to be served by enforcement of the socio-economic right is weighty, the Commission has the special obligation to find a way of practical enforcement.

The notion that essential goods require differential treatment is widely accepted. In a January 29, 2001 speech at Davos,[8] Dr Gro Harlem Brundtland, the then Director-General of the World Health Organization (WHO), said:

> We need to define key global public goods: Together, we need to identify areas in which the *production and dissemination of essential goods at a reasonable price cannot be assured through normal market forces*. In the health field, this includes essential vaccines, diagnostics, and medications.

The European Union, like other governments, singles out essential goods for special treatment under a variety of laws. For Example, Article 36 of the Charter of Fundamental Rights of the European Union "recognizes and respects access to services of general economic interest in order to promote the social and territorial cohesion of the Union."[9] The Constitution of Ireland specifically provides that "the operation of free competition should not be allowed so to develop as to result in the concentration of the ownership or control of essential commodities in a few individuals to the common detriment."[10]

According to the Expert Report by Professor Scherer:[11]

> In the United Kingdom, Section 41 of the Patents Act of 1949 distinguished foods, medicines, and surgical devices from other patent-protected products by articulating a rebuttable presumption in favor of compulsory licensing to ensure that the products are "available to the public at the lowest prices consistent with the patentees' deriving a reasonable advantage from their patent rights." Between 1953 and 1971, a total of 20 compulsory licenses were granted in response to 54 applications, covering inter alia such important products as Chloromycetin, Librium, and Valium.

There are many diverse approaches to determining which goods are essential.

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[8] Dr Gro Harlem Brundtland, "Addressing the challenges of unequal distribution," World Economic Forum, Plenary Seminar, January 29, 2001.

[9] In a March declaration, the Centre Européen des Entreprises à Participatio Publique et des enterprises d'intérêt économique general (CEEP) asked the European Union to ensure that policies on competition "be balanced by other fundamental objectives, among them fulfilling the tasks of general interest...with this prospect in view, the Union should not start from general principles, but from the purposes of services of general interest – i.e. responding to the needs and expectations of users, and of society at large. These include in particular: guaranteeing everyone the right of access to essential goods and services, which means that Article 36 of the Charter of Fundamental Rights has to be given substance and implemented; promoting social and territorial cohesion, as an expression of the Union's general interest, which requires developing Article 16 of the Treaty; creating conditions for sustainable development, competitiveness and meeting the requirements of future generations." CEEP.02/AVIS.03 Orig. Fr. – March 2002.

[10] 1st July 1937 (Last modification: 7 November 2002), Article 45.2.

[11] Expert Report, Professor FM Scherer

India has an essential commodities act, which provides broad authority to review prices and commercial practices for 18 categories of essential commodities.[12] Many countries exempt essential goods from sales or VAT obligations. For example, Namibia exempts diesel, oil, mahangu and maize meal from the VAT,[13] and several US state governments exempt food, low priced clothing items and medicines from state sales taxes. Partners in Population and Development, an inter-governmental alliance of sixteen countries[14] created to improve and accelerate the transfer of knowledge, expertise and skills in the fields of population and development through South-to-South collaboration recently issued a statement calling upon member countries to take steps to protect "access to essential drugs and commodities for reproductive health . . . [and] to protect their capacity to provide essential drugs and commodities at the lowest possible cost. This includes rights to parallel importation, compulsory licensing and local manufacture of essential drugs and commodities." [15] Some other definitions go considerably further. A recent UK Rural White Paper considered broadband Internet access an "*essential service"* because it provides access to "the latest entertainment, education and training."[16] The Tokyo Declaration on the Asia Pacific perspective on the World Summit on the Information Society (WSIS) took a similar tack,[17]

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[12] Essential Commodities Declared under the Act include:

1. Cattle fodder, including oilcakes and other concentrates.
2. Coal, including coke and other derivatives.
3. Component parts and accessories of automobiles.
4. Cotton and woolen textiles.
5. Drugs.
6. Foodstuffs, including edible oilseeds and Oils.
7. Iron and Steel, including manufactured products of Iron & Steel.
8. Paper, including newsprint, paperboard and strawboard.
9. Petroleum and Petroleum products.
10. Raw Cotton, either ginned or unginned and cotton seeds.
11. Raw Jute.
12. Jute textiles.
13. Fertilizers, whether inorganic, organic or mixed.
14. Yarn made wholly from cotton.
15. Exercise Books.
16. Insecticides, Fungicides, Weedicides and the like.
17. i) seeds of food crops and seeds of fruits and vegetables,
    ii) seeds of cattle fodder and
    iii) jute seeds.
18. Onion.

[13] October 15, 1999 - "Essential commodities to be exempted from VAT," *The Namibian.*

[14] Bangladesh, China, Colombia, Egypt, The Gambia, India, Indonesia, Kenya, Mali, Mexico, Morocco, Pakistan, Thailand, Tunisia, Uganda and Zimbabwe.

[15] MEDIA RELEASE, Partners' countries call for essential commodities security, 18 April 2001.

[16] *Our Countryside: The Future - A fair deal for rural Britain*, November 2000. See also Tim Hirsch, "Digital divide 'hits rural business' A widening 'digital divide' between town and country is holding back the UK's rural businesses, a watchdog is warning." 7 May 2003. *BBC.*

> "Lack of broadband access can present an expensive obstacle to new rural businesses, denying them market for their products and services. New technologies, such as broadband, also offer residents access to essential services that no longer have a physical presence locally." [Countryside Agency Chairman Sir Ewen Cameron] said "young people living in remoter areas needed the same access to the latest entertainment, education and training, delivered through broadband, if they were not to feel disadvantaged compared with their urban counterparts."

[17] "High-quality access, attainable through broadband, has great potential to help better deliver essential services required to meet basic human needs through applications such as e-education and e-health, as well as e-business and other ICT applications. Also, new technologies, such as wireless and satellite networks can assist remote areas, including small island nations, to gain access to information and knowledge." Statement on behalf of

noting that high speed Internet connections had the forward-looking *potential* to "deliver essential services required to meet basic human needs through applications such as e-education and e-health, as well as e-business."

Governments adopt a wide range of policies regarding essential goods. Tax policy often provides preferential treatment to categories of essential goods, and governments provide a variety of subsidies, price controls, direct state provision of goods and other interventions to promote more universal access to goods on terms that are considered fair.

There is a rich economics literature discussing the rationales for *commodity egalitarianism,* a term that describes the common case where governments (and societies) support more equal access for certain goods, while tolerating greater inequality for other goods. The World Trade Organization, by consensus of all member countries, declared in the Doha Declaration on TRIPS and Public Health that medicines were special commodities that *can and should* receive special treatment in intellectual property laws.

> 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.[18]

Distinctions are often made regarding which specific goods qualify (*or do not qualify)* as essential with broader categories. In the US, food stamps can be used for some food purchases (such as fresh vegetables, milk, meat, bread, etc), but not others (candy, some prepared foods, etc), and local telephone service was considered particularly essential (and priced to be affordable to the poor), while long distance calling was considered less essential (and cross-subsidized local calling rates). Virtually every nation that subsidizes pharmaceutical purchases also limits coverage according standards of care.

HAART treatment, which is needed for the survival of approximately 5 million persons living with HIV in South Africa, is appropriately considered an essential good.

representatives of the governments of 47 countries, 22 international organizations, 54 private sector entities and 116 non-governmental organizations (NGO) of the Asia-Pacific region gathered at the Asia-Pacific Regional Conference, held in Tokyo from 13 to 15 January 2003.

[18] Declaration On The Trips Agreement And Public Health, Adopted 14 November 2001. Paragraph 4.

SECTION 5: INTELLECTUAL PROPERTY GOODS

The evaluation of excessive pricing is different when the price of the goods is based upon the value of intellectual property. This principle is based upon the unique characteristics of the costs and prices of intellectual property.

5.1 Non-Rival in Consumption

Intellectual property is "non-rival" in consumption. As described by Professor Baruch Lev, the key difference between intellectual or knowledge goods from physical goods or services is that the former is "non-rival in consumption."[19]

> One thing differentiates intellectual capital or knowledge assets from physical and financial assets, and that's what economists call "rivalry" and "non-rivalry" assets. Physical assets are rival assets. Different users rival for the use of an asset. This asset cannot be used elsewhere at the same time. If American Airlines assigns an airplane to a specific route, it cannot assign the same airplane and crew, at the same time, to another route. And the financial capital that's invested in the airplane cannot be assigned to another route. This means that if you have to increase production and you're working relatively close to capacity, you have to substantially increase the investment in physical assets. Physical, human and financial assets are rival, or scarce, assets, where the scarcity is reflected by the cost of using the assets. On the other hand, intangible assets are non-rival assets.
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> The use of an asset in one case does not prevent it from being used simultaneously by others in another case. So if I use the example of American Airlines' reservation system — which is the intellectual capital…it can be used at the same time by 10 people, by 10,000 people, by 10,000,000 people. There's no limit to this and no opportunity is lost. If you want to increase the production of a patent, a drug, a software, or double it, triple it, quadruple it, you don't have to increase the investment in R&D at all.
>
> This is what some people call "scalability" or the ability, after you've made the first initial investment in intellectual capital, to scale it endlessly and enjoy increasing returns. And if you know how to work your market you can get huge value out of it. So this non-rivalry attribute of intangibles is the main thing that differentiates intangible assets from physical assets.

In practice, the distinction between intellectual property and physical goods is not always precise, because many goods have characteristics of both (a point elaborated below). However, when prices for a good are largely based upon the value of the intellectual property, it is useful to consider the good as an intellectual property good.

As noted by Professor Lev, increases in the production of a drug do not require increased investments in research and development (R&D), and unlike the case with a physical good

[19] Baruch Levy, quoted in "Measuring the Value of Intellectual Capital," MARCH/APRIL 2001 · *Ivey Business Journal.*

that is costly to replicate, it is at least economically feasible within a fixed budget for the poor to expand access. This is one reason that intellectual property goods should be evaluated differently.

5.2 Prices Determined by Value of Good to Consumer

Another reason for intellectual property goods to be considered differently concerns the way prices are set. Prices for intellectual property are typically determined by demand rather than supply considerations. The price one pays for a recording of Miriam Makeba or the Rolling Stones has nothing to do with the "cost" of production, but rather with the value assigned to the good by the consumer. Likewise for best-selling books, hit movies, and for most of the important patented medicines, prices are typically determined according to what the buyers will pay, rather than what it "costs" the seller to produce the good. Thus, products with significant public R&D subsidies, such as Retrovir /AZT, Zerit/d4T, Norvir/Ritonavir, Ziagen/Abacavir, Gleevic, Paclitaxel/Taxol or Ceredase were priced very high when introduced into the market, despite the fact that the government had paid for much of the most risky stages of R&D for products.

That is not to say that there is no connection between the prices and the supply of intellectual property goods. Clearly the larger the commercial market for intellectual property goods, the greater the private investment in the supply of such goods. The larger the commercial market for medicines, the larger will be the private investment in R&D for new medicines, all other factors being equal.[20]

This is the policy dilemma. Once an intellectual property good is created, it can be copied for little or no cost. Society needs a system to ensure that the good is created in the first place, but that system must also be fair. If prices are so high that most persons cannot afford essential intellectual property goods such as medicines for HIV, are they "reasonably related" to the economic value of the good? Or are these prices excessive and therefore illegal?

[20] However, as noted in the Expert Report by James Love on R&D, the are many inefficiencies in private markets, and in response, substantial public subsidies for medical innovation.

SECTION 6: STANDARDS FOR EXCESSIVE PRICING OF ESSENTIAL INTELLECTUAL PROPERTY

For essential intellectual property goods in South Africa, a price that bears a reasonable relationship to the *economic value* of a good *must at least* be a price that *most people* in need of the good are willing and able to pay for it. A price that is too high for most people to afford is presumed to be excessive.

The test of affordability does not go as far as the policies reflected in the Canadian Patent Act until 1992 as well as in the UK Patent Act of 1949, which stated that the price of a medicine should be the *lowest price* consistent with giving to the patentee due reward for the research leading to the invention and for other factors.[21] A product could be both affordable and excessively priced, a common finding in public utility ratemaking proceedings, for example.

To rebut the presumption that a price is excessive based upon evidence that it is not affordable to a significant number of persons, the seller of an essential intellectual property good must demonstrate that the good is being sold at the lowest possible price consistent with giving to the patentee due reward for research and other legitimate costs of developing the good.

A patent holder may meet its burden through one of three possibilities:

(a) The owner of the intellectual property has instituted an open licensing programme – i.e. a standard form non-discriminatory license programme -- at reasonable royalties and competitive provision of the product is economically feasible;[22] or

(b) Competitive provision of the good is not economically feasible and the prices are reasonable in light of the cost of making the good available;[23] or

(c) The given prices are necessary to generate the income needed for the development of the good because, e.g., there is not a substantial market for the good in countries defined by the World Bank as high-income economies.[24]

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[21] Section 41(4) of Canada's 1969 Patent Act instructed 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 described." Evaluation of Essential Facilities and Exclusionary Acts, Section 2. "In the United Kingdom, Section 41 of the Patents Act of 1949 distinguished foods, medicines, and surgical devices from other patent-protected products by articulating a rebuttable presumption in favor of compulsory licensing to ensure that the products are "available to the public at the lowest prices consistent with the patentees' deriving a reasonable advantage from their patent rights." Expert Report, Professor FM Scherer. *See also* Jerome Reichman with Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: The Canadian Experience*, UCTAD/ICTSD 34 (October 2002). Section 41 of the UK Patent Act of 1949 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". Love, James. *Compensation for Non-Voluntary Use of a Patent* (Expert Report JL(R)).

[22] In such a case, it may be presumed that market forces will produce the lowest possible price while giving the patent holder due reward through royalty payments.

[23] This test would apply to products such as Alglucerase (Ceradase®), for which it may not be economically efficient for generic entry because of small size of the market or for other reasons.

SECTION 7: APPLICATION OF THE STANDARD

The standard is applied as follows:

1. There is overwhelming evidence that the prices charged for AZT, 3TC, Combivir and NVP are not affordable to most persons living with HIV in South Africa. The best evidence of this is the fact of lack of access to HAART treatment.
2. The competitive provision of the good is feasible, and indeed, there are in fact several generic firms already manufacturing the products in markets outside of South Africa.
3. There is a substantial market for the products in countries defined by the World Bank as high income.
4. The firms have refused to issue non-discriminatory licenses in return for reasonable royalties.

The patent owners had the opportunity to either price their medicines to be affordable to most people, or to license their patents to competitors in return for reasonable royalty (permitting competition to lower prices and increase access). They have chosen instead to engage in restrictive licensing practices, and to set prices that only a tiny fraction of persons living with HIV could afford. We therefore conclude that excessive pricing has been established in this case.

[24] This standard would not apply in cases such as this where the medicine in question was developed primarily for markets in high income countries.

SECTION 8: ELABORATION AND THE APPLICATION OF THE STANDARD

As noted by Professor Fox and many other commentators, the practical issues in reviewing allegations on excessive pricing can be daunting, and this has often led to considerable caution in applying competition policy sanctions for excessive pricing. Competition authorities do not want to become offices of price controls. This is particularly true for cases where the standards for determining if a price is excessive are based upon the costs of providing the good, which may lead to inquiries that may be time consuming, resource intensive and controversial.

Many of the excessive pricing cases begin with a comparison of a price in one market to the prices charged either for the same good in a different market, or for similar goods. Competition authorities then undertake an analysis of the rationales that might be legitimate for charging higher prices in a particular market, such as when higher prices are performing normal pro-competitive functions such as inducing entry and innovation, allocating scare supplies to higher valued uses or rewarding higher quality of convenience.

For intellectual property goods, different approaches can be used, which in some cases will eliminate the need for the type of information gathering that might be associated with an analysis of the pricing of a physical good or a service. For an essential medicine, it should normally be sufficient to simply review evidence regarding the access to the product to conclude that the intellectual property (the patent) should be licensed on a non-discriminatory basis for a reasonable royalty. Even when a defence is asserted that the price does not constrain affordability, it would not be necessary to investigate the product costs, since the only issue in dispute would be whether or not the prices should be considered affordable to most consumers.

The best evidence of affordability will be the actual market outcomes in South Africa. If one wants to argue that only barriers *other than price* block access, the seller would be expected to produce evidence that prices are affordable somewhere, when reasonable adjustments are made for differences in purchasing power. (See discussion below for benchmarks).

There would be two cases where the evaluation for essential intellectual property would necessarily involve an assessment of costs. In the first case, described above as defence (b) to a presumptive finding of excessive pricing, if the barriers to generic entry were too high and a product was a natural monopoly, the only recourse would be to evaluate costs. This will not be the situation for the current products used in HAART, but it will be the case for some products that have very small patient populations and high production costs, or which are protected by trade secrets.

The other case is described above as defence (c), where the intellectual property good does not have a substantial market in countries defined by the World Bank as high-income economies, and the unaffordable prices are necessary to induce the investment to create and market the good. This case is distinguished from that of goods that have a substantial market in high-income economies as follows. For goods that have as their primary market wealthier countries, reductions in prices in lower-income countries will be much less important in determining investment decisions. For example, for medicines in general, Africa as a whole is about 1.3 percent of the global market. By itself, South Africa represents only about .3 percent of the global pharmaceutical market. On the other hand, if a good does not have a

substantial market in higher income countries, then it may not be feasible in low income countries to price even essential products to be affordable -- a question that would be resolved by examining seller costs. None of the medicines currently used for AIDS would fit this definition, since they all have significant markets in the wealthier countries.

This is a particular framework for evaluating essential intellectual property goods. *It is not the model for evaluating any other good.* Non-essential intellectual property goods would not be required to be priced so they are affordable to most persons, and neither would essential physical goods or services. *For all goods that are not defined as essential intellectual property goods, different tests and benchmarks would be used to evaluate allegations of excessive pricing.*

The following is an analytical model to illustrate the framework for considering a wide range of excessive pricing complaints. The reason to present this framework here is to better demonstrate the unique nature of the tests applied to essential intellectual property goods, and to build confidence that this approach is appropriate for South Africa, and will permit the Competition Commission to effectively manage excessive pricing disputes.

SECTION 9: FRAMEWORK FOR EVIDENCE OF EXCESSIVE PRICING

The statute asks if a price "bears no reasonable relationship to the economic value of the good . . . to the detriment of consumers." Thus, the price must not only be high to be excessive, it must be higher than is reasonable, and the high price must harm consumers.

To answer this question, a general framework for considering excessive pricing is presented -- one that can be applied to a wider set of goods. The notion that *"one size fits all"* is rejected, in favour of a framework that recognizes the different social norms regarding access to essential goods, and the different factors that typically drive both costs and prices for intellectual property and for physical goods and services.

The first step is to divide all goods into three categories -- essential, non-essential and luxury goods. This division reflects the reality that social norms accept higher levels of inequality for luxury goods than non-luxury goods, and expects more equal access to essential goods. The actual allocation of products to these categories is a matter of judgement, and will change over time. For example, at one time, electricity or telephone service was once considered a non-essential good, but increasingly these services are considered essential. And within broad sectors, further distinctions can be made. For example, within the food sector, there are staples that would be considered essential, and other products that would be considered either non-essential or luxury items.

1. Essential goods are those goods that society seeks to promote universal or equal access.

2. Non-essential goods are those goods for which society accepts a higher degree of inequality in consumption.

3. Luxury goods are goods that are not marketed for mass-market consumption. Indeed, in some cases, the limited access to a luxury good is part of its appeal.

Changes in prices will influence notions of what is essential. The WHO and the Republic of South Africa (RSA) Department of Health (DOH) both maintain lists of essential medicine, but these lists are quite limited, because they often imply an obligation by governments to fund treatments. Historically very few patented medicines have been included in WHO essential drug lists, because prices for patented medicines are high, and governments with limited resources avoid expensive purchases. Indeed, only in April 2002 did the WHO include any ARV products on its essential drug list, because the prices had been so high. Many important medicines for cancer, diabetes, asthma, and opportunistic diseases are not on official WHO or RSA MOH essential drugs lists, but they are clearly essential for good health.

In this analysis, because we do not take market prices as the only feasible outcome, we consider any medicine that is used in standard health care or that is needed to treat diseases that have significant morbidity and mortality to be essential, regardless of its current price or availability. As noted, this will always be more inclusive than the WHO or RSA MOH essential drug lists, which are typically limited because of concerns over affordability.

9.1 Intellectual property and physical goods and services

Following the division into essential, non-essential and luxury goods, the next step is to distinguish between intellectual property, which if copied can be non-rival in consumption, and physical goods and services, which cannot. In practice, many goods have some mixture of intellectual property and physical properties, and the decisions regarding classification will depend upon judgements and evidence of how markets operate. Clearly medicines have both physical goods and intellectual property characterises. Pills are something you can hold in your hand and swallow. But the pricing of patented products bears almost no relationship to the costs of making the physical copies. Bread is made according to a recipe, but given the wide availability of alternative recipes *(including many in the public domain),* prices generally are related to costs. Houses are built according to blueprints, but the price of a house is driven by the costs of inputs, including land. Consumer electronics, like cell phones, include chips and are based upon hundreds of patented technologies. But patents on consumer electronics are typically licensed on non-exclusive terms and often limited to around 5 percent of the competitive costs of the products, so manufacturing costs drive prices, and the products would appropriately be considered as a physical good. Fashion goods like designer goods or even Levi jeans are both physical goods and intellectual property protected by trademarks. When the value of intellectual property is the primary factor in determining prices, the good should be evaluated as an intellectual property good. When the costs of inputs are the primary factor, the good should be evaluated as a physical good.

The significance of the category for intellectual property is that it recognizes the fact that a good can be cheaply copied to expand access. While it may be possible to reduce the price of a medicine by 98 percent *(the decrease in the global price of 3TC from the levels charged by GSK following the introduction of generic competition)* by removing the exclusive marketing rights normally associated with a patent, the same cannot be said for most essential food or housing goods.

Table 3 provides an illustration of how different goods might be allocated on the basis of essential, non-essential or luxury goods, and between intellectual and physical goods (and services). This list is not definitive, but useful in explaining the basis for the particular treatment that will be used to analyse the market for essential medicines.

Table 3: Illustration of Allocation of Goods in Categories for Purposes of Analysis for Essential Goods

Ability to copy at low cost?	Sector	Essential	Non-Essential	Luxury
Intellectual Property	Medicine	Drugs to treat diseases that have significant morbidity and mortality	Medicines for cosmetic purposes	
	Software	Client operating systems and applications essential to operate in areas of strong standardization (i.e. MS Windows, MS Word)	Server software, non-essential applications, applications where standards do not restrict competition, consumer video games	
	Journals and Textbooks	Essential reference materials for primary and secondary education	Specialized publications for industry	
	Entertainment		Movies, recorded music	
	Fashion goods / Art		Silk scarf	Coach bags
Physical Goods / Services	Food	Staples	More expensive food items, cola, chips, meals at restaurants	Gourmet food
	Physician/dental services	Preventive and basic health services, treatment for diseases of significant morbidity and mortality, basic dental care	Cosmetic surgery, cosmetic dental work, health care that exceeds accepted standard of care	
	Housing	Essential Housing	Better housing	
	Utilities, fuel, etc	Water, electricity, home telephone service	Business telephone use, gasoline, cellular telephone service	
	Consumer electronics		Television, radio, DVD players	
	Computers	Computers for schools and libraries	Computers for business use, government	

Table 4 is an illustration of how prices would typically be determined in the various categories for goods. For intellectual property, prices are normally based upon the value to the consumer. For essential and non-essential categories, prices for physical goods and

services are normally driven by costs[25]. These are broad generalizations of course, but appropriate for this analysis.

Table 4: Typical Market Pricing Outcomes

Ability to copy at low cost?	Essential	Non-Essential	Luxury
Intellectual Property	Prices determined by value to consumer	Prices normally based upon value to consumers	Prices normally based upon value to consumers
Physical Goods / Services	Prices normally related to costs	Prices normally related to costs	Prices based upon a variety of cost and value factors

Table 5 provides a general standard for allocation of enforcement resources. The more essential the good, the more resources allocated to enforcement.

Table 5: Standards for allocation of enforcement resources

Ability to copy at low cost?	Essential	Non-Essential	Luxury
Intellectual Property	More enforcement resources	Standard Enforcement	Less enforcement resources
Physical Goods / Services	More enforcement resources	Standard Enforcement	Less enforcement resources

Table 6 provides the standards for what constitutes an essential price. In this analysis, prices for any goods would be considered excessive if priced unreasonably high relative to benchmarks based upon prices charged for other goods or other markets. But for essential intellectual property goods, a separate standard would also apply -- prices would be presumed to be excessive if they were higher than what was affordable by most people, regardless of comparisons to other prices for other goods or markets.

Table 6: Standards for evaluation of excessive pricing

Ability to copy at low cost?	Essential	Non-Essential	Luxury
Intellectual Property	**Goods not affordable to most people** Or Goods priced excessive relative to benchmarks	Goods priced excessive relative to benchmarks	Goods priced excessive relative to benchmarks
Physical Goods / Services	Goods priced excessive relative to benchmarks	Goods priced excessive relative to benchmarks	Goods priced excessive relative to benchmarks

[25] For luxury goods and variety of factors may come into play.

9.2 Affordability of Essential Intellectual Property Goods

The rationale for a different standard for essential intellectual property goods flows from the cost of making additional goods available. Essential housing could be unaffordable, but it is costly to make additional units of housing, and also not reasonable to ask that private parties make housing available at prices below their costs. However, with intellectual property goods, prices are based upon the value to the consumer and not on the costs of production. A decision to price an essential good so that it is only available to the most affluent consumers is not considered appropriate. For most important new medicines to treat AIDS, cancer or diabetes, patent owners seek to price goods as high as possible, but nonetheless, it is not considered appropriate to price products so high that most people are excluded from access. When the price of CIPRO was considered too high to permit broad access to an important treatment for a biological warfare attack of antibiotic resistant strains of anthrax, the US and Canadian governments threatened Bayer with an override of the exclusive patent rights if the price of CIPRO was not lowered *(Bayer lowered the price)*. Provinces in Canada and several European governments have threatened to override patents on the BRCA breast cancer gene patents, in order to expand access to genetic testing. The UK recently prosecuted an excessive pricing case against Genzyme over high pricing for Ceredase, a drug for treatment of the severe and rare illness Gauchers Disease. Brazil has threatened to issue compulsory licenses for two ARV products (Efavirenz/Stocrin and Nelfinavir/Viracept) because the high prices undermined the feasibility of providing universal access to HAART treatment. Brazil also threatened to issue a compulsory license for Glivec, a very expensive treatment for a rare form of Leukaemia, on the grounds that the public sector could not afford the cumulative costs of very high prices for treatments for severe diseases, even when the particular disease has a small number of patients. For essential medicines, universal access is an accepted goal, as evidenced by countless international resolutions, including recently the *Doha Declaration on TRIPS and Public Health*, which says that member states have an affirmative obligation to implement national patent laws in a way promotes access to medicine for all.

9.3 Defences

Table 7 notes the defences that may be used in an allegation of excessive pricing.

1. For any good, high prices may always be justified by the cost of providing the good or service. (Although in the case of essential intellectual property goods, this only applies if open licensing is not a viable alternative).

2. When looking at access to essential intellectual property goods, where there is an obligation to price a product to be affordable for most people, access may be constrained by non-price factors beyond the control of the seller.

3. For intellectual property goods, a seller may also raise as a defence the fact that a patent (or other exclusive right) has been licensed on a non-discriminatory basis to all competitors in return for reasonable royalty. If the right is a patent, the owner of the patent can offer a standard form license-of-right under the RSA patent law. (*An extensive discussion of the reasonable royalty is provided in Export Report JL-R.)* This defence would normally be sufficient in cases where competition for the good is feasible if the patent is available for non-

discriminatory licensing on reasonable terms, and there is no collusion between parties.

Table 7: Defences to allegations of excessive pricing

Ability to copy at low cost?	Essential	Non-Essential	Luxury
Intellectual Property	Intellectual Property has been licensed to competitors on reasonable terms, or if not, Access constrained by non-price factors or if not, High prices justified by costs	High prices justified by costs, normal commercial practices	High prices justified by costs, normal commercial practices
Physical Goods / Services	High prices justified by costs	High prices justified by costs, normal commercial practices	High prices justified by costs, normal commercial practices

9.4 Benchmarks

Table 8 provides a non-exclusive illustration of the benchmarks that can be used to evaluate allegations of excessive pricing. These include the following:

1. For all goods, are prices excessive relative to prices charged in other markets and countries?
2. For all non-luxury intellectual property goods, are prices excessive relative to prices charged in countries of similar purchasing power?
3. For all non-luxury physical goods and services, are prices excessive relative to costs?
4. In determining affordability for essential intellectual property goods,
    a. Is access actually constrained by pricing? If so, pricing is assumed to be excessive *(subject to defences)*.
    b. An alternative to (a) when insurance, state provision or other mechanisms to pool resources do not exist is to compare prices relative to household budget shares for medicine. *(Based upon budget shares for medicines that are supported by evidence.)*
    c. Are prices affordable when compared to prices in countries where products are widely available? For example, are RSA prices affordable when adjusted for relative GDP per capita/patient, or other special factors, such as unequal distribution of incomes?

Table 8: Possible benchmarks for excessive pricing

Ability to copy at low cost?	Essential	Non-Essential	Luxury
Intellectual Property	1. Is access constrained by pricing? 2. Are prices affordable when compared to countries where prices are universally available, adjusted for relative GDP and other special factors. 3. For medicine, consider prevalence and availability of mechanisms to pool costs	Are prices excessive relative to prices charged in markets / countries of similar purchasing power practices?	Are prices excessive relative to prices charged in other markets / countries?
Physical Goods / Services	1. Are prices excessive relative to prices charged in other markets / countries? 2. Are prices excessive relative to costs?	1. Are prices excessive relative to prices charged in other markets / countries? 2. Are prices excessive relative to costs?	1. Are prices excessive relative to prices charged in other markets / countries?

SECTION 10: BENCHMARKS FOR ESSENTIAL MEDICAL TECHNOLOGIES

Table 9 provides five benchmarks for assessing whether a price for an essential medical technology in RSA is excessive.

1. The first test is to compare the ratio of *access to need* for a medicine in RSA to a reference country, to determine if the good is in fact affordable in other countries, and to evaluate the reasonableness of access in South Africa. The reference country would be one that has a more acceptable ratio of access to need. For example, for HAART treatment, one would likely look at developed economies such as the United States, Canada, France, Italy, Germany, Spain or the UK, or a developing economy such as Brazil where HAART treatment is generally available. The ratio is a benchmark of how access in South Africa differs from the reference county.

2. The second test is a general test for the affordability of prices of products that are purchased from out-of-pocket funds. The price in the country with access is adjusted according to the relative ratios of per capita GDP. The United States has a significant population that does not have a prescription drug private or social insurance benefit. Very few US citizens can afford HAART treatment without third party payments. However, some chronic treatments for chronic illnesses may be a proxy for a price that would be considered affordable for a significant number of uninsured persons.

3. The third test is the same as the 2nd test, except that it uses the ratio of wages for workers. This test can be adjusted to take into account inequality and inequality of access even in the reference country. For example, one could take as the reference a higher wage group in the United States that actually has an acceptable level of out-of-pocket access, and compare to a lower wage tier wage group in RSA that does not have access, to see if the adjusted prices in RSA can be considered unaffordable.

4. Test 4 is for products that are only realistically widely available through pooled payment mechanisms such as insurance or direct reimbursements by the government. Drugs for many severe illnesses are now financed this way. The ratio is the same for test 2, but it only provides a measure of affordability if the client population has access to the pooled payment mechanisms. The upper bound on prices for test 4 will be higher, because several households will pool resources to contribute to the treatment costs.

5. Test 5 is similar to 4, but it makes an adjustment for the case where the prevalence of the disease is high enough to place burdens on the pooled payment mechanisms. This is the relevant test for HAART treatment in RSA, as it is widely recognized that HIV prevalence in Southern Africa is extraordinarily high, placing huge burdens on health care payment systems.

Table 9: Benchmarks for Excessive Prices of Medicine: Comparison to Prices in Countries where access is not constrained by price

Test	Situation	Benchmark	Comment
1	Ratio of coverage in RSA to coverage in reference country	. $CoverageRatio = \frac{ACCESS_{RSA}/NEED_{RSA}}{ACCESS_{RC}/NEED_{RC}}$	This benchmark tests the reasonableness of the lack of access in RSA based upon access in the reference country
2	Reference product is affordable when purchased out of pocket.	$P^* = P_{RC} \div \frac{GDP_{RC}/POP_{RC}}{GDP_{RSA}/POP_{RSA}}$	Adjusted for relative income as measured by GDP per capita
3	Reference product is affordable when purchased out of pocket. Analysis focuses on unskilled wage earners	$P^* = P_{RC} \div \frac{WAGE_{RC}}{WAGE_{RSA}}$	Adjusted only for relative wages of unskilled workers
4	Reference product is affordable in country when resources are pooled (reimbursed by state or insurance)	$P^* = P_{RC} \div \frac{GDP_{RC}/POP_{RC}}{GDP_{RSA}/POP_{RSA}}$	Adjusted for relative GDP per capita
5	Reference product is affordable in country when resources are pooled (reimbursed by state or insurance) and high prevalence of disease places high burden on pooling mechanisms.	$P^* = P_{RC} \div \frac{GDP_{RC}/HIV+_{RC}}{GDP_{RSA}/HIV+_{RSA}}$	Adjusted for relative GDP per infected person

P_{RC} is the price in the reference country.
P is price assumed to be affordable in RSA.*

10.2 Application of benchmarks to ARV products in RSA

The appropriate tests of prices for the RSA market would be tests 2 and 5.

10.2.1 Test 2, Reference to Product for Chronic Illness that is Affordable In Reference Market

Test 2 looks at the affordability of a product for a chronic illnesses that is affordable to uninsured persons. The reference country is the United States, the only developed economy without national health insurance. For the price of the reference product, we use the average annual wholesale cost of drug therapy for the top 50 drugs for senior citizens, weighted by expenditures on each drugs. The data are from a Families USA study, *Out-of-Bounds: Rising Prescription Drug Prices for Seniors*,[26] which in fact argues that these prices are not affordable. This is taken as the upper bound on affordable prices for chronic conditions. The study reports a January 2003 average annual prescription cost of $1,429. In 2002, the US per capita GDP was 15.24 times the GDP per capital in South Africa. The raw benchmark price is $1,429/15.24 = $93.82 per year.

South Africa has a particularly unequal income distribution. If the test is applied to the lower 90 percent of the South African population, which has 55 percent of the national income, the benchmark price is $57. If one only looks at the bottom 20 percent of the income distribution, the affordable price would be $13 per year. This can be compared to the price of a HAART cocktail. In Table 10, the benchmark price and the relationship of the benchmark price to a HAART regime of Combivir+NVP is reported. The wide gap between the benchmark and the actual GSK/BI prices is consistent with the evidence that prices are not affordable out-of-pocket in South Africa.

Table 10: Test 2 Benchmark by Income Decile: Annual Cost of Medicine for Chronic Illness Paid Out-of-Pocket, Adjusted for relative per capita GDP, Prices in US dollars

RSA Income Decile	Benchmark Price in USD	GSK/BI price for Combivir/NVP as percent of benchmark price
1	424	504%
2	166	1,288%
3	107	1,999%
4	73	2,930%
5	52	4,113%
6	38	5,629%
7	29	7,376%
8	22	9,722%
9	16	13,368%
10	10	21,389%

[26] Out-of-Bounds: Rising Prescription Drug Prices for Seniors, Families USA Publication No. 03-106, 2003 by Families USA, Washington, DC 20005, publication is available online at (www.familiesusa.org).

10.2.2 Test 5, Reference product is affordable in country when resources are pooled (reimbursed by state or insurance) and high prevalence of disease places high burden on pooling mechanisms.

The point of Test 5 is to examine the situation where patients in both countries benefit from private or state insurance for medicine, but the prevalence of the disease was particularly high in South Africa, placing a burden on the pooling mechanisms. The reference product is a HAART regime of (AZT+3TC/Combivir) +NVP, which cost $10,914 at the US based DrugStore.com. The GDP per person living with HIV in the USA is $11.574 million, which is somewhat lower than France and Canada, and much lower than the UK, Germany or Japan. The GDP per person living with HIV in South Africa is $ 20.85 thousand. The national resources per person living with HIV are 555 times higher in the US than in South Africa. If the US price for the HAART regime is adjusted for relative GDP per person living with HIV, the benchmark price is $19.66, per year. The VAT inclusive BI/GSK wholesale price for this same HAART regime was $2,138.90 in July, or more than 100 times the benchmark price.

APPENDIX A: MARK-UP FROM GENERIC COST MODEL

The "economic value of the good" can be defined either as the *cost* of creating, manufacturing and distributing the good, or in terms of the *value* of the good to consumers.

The complaint presents an analysis of the GSK and BI pricing that is based upon the *cost* of the good, as measured by a particular economic model. In this model, a non-excessive price for an ARV medicine must be reasonably related to the manufacturing, distribution, marketing and R&D costs of the product, based upon benchmarks from generic alternatives, plus additional allowances based upon standard big pharma industry ratios to account for R&D costs and profit margins. This is calculated as the sum of the cost of the lowest global price for a generic alternative, which is taken as a proxy for manufacturing and distribution costs, plus allowances of 15 percent for investment in R&D, 15 percent for profit and a 14 percent VAT. *[1/(.7*.86) = patent owner costs are estimated at 166 percent of the generic price[27]]*. Table 11 presents an illustration of this test. The private sector prices charged for 3TC, AZT, Combivir and NVP are all significantly higher than the benchmark prices.

Table 11: Benchmarks for Reasonable Price using 166 percent of Generic Cost Method (Daily price in USD of ARV products)

Drug	Formulation	Quantity	July 03 Brand Price (inclusive of VAT)	May 03 Best Generic Price	Estimate of Reasonable cost (inclusive of VAT)	Ratio of Brand to Benchmark
AZT	300mg	2 Tabs	2.94	0.38	0.63	466%
3TC	150mg	2 Tabs	3.23	0.18	0.30	1,080%
AZT+3TC	300 + 150 mg	2 Tabs	4.04	0.56	0.93	434%
NVP	200mg	2 Tabs	1.82	0.29	0.48	379%

The *166 percent of generic cost* benchmarks combined with the finding of dominance and the enormous social cost associated with the lack of access to medicines provides a reasonable basis for a finding that the GSK and BI prices violate the provisions of the Act on excessive pricing.

There are objections to this model for excessive pricing of medicines. One is that the cost factors are controversial, and may require time consuming and resource intensive investigation into each one. For example, the patent owners may assert that the R&D and profit margins are too low, either in percentage terms or in relation to the base, and consumers may allege they are too high, such as in the case where development of a product was supported by public funds, or where the profit margins reflect monopoly pricing. *In this proceeding, GSK and BI both refused to disclose financial data on product specific*

[REDACTED]

[27] Put another way, the best global generic price is considered to be 60 percent of total cost of the product to consumers, inclusive of the two 15 percent margins for R&D and profits and the RSA VAT.

A more fundamental and general criticism of the *166 percent of generic cost* approach for some other ARV products is that it relies on the existence of an efficient and competitive generic market as a benchmark for manufacturing and distribution costs. If an efficient competitive generic sector price is not available, the approach fails. This is evident when one looks at the prices of generic products over time.

Table 12 reports the prices for generic ARV products manufactured in Brazil from 1996 to 2000, when Brazil was primary market for generic ARV products. Each of the products fell in price over the 5-year period. AZT dropped in price by 68 percent, ddI 72%, 3TC 71%, and in four years d4T decreased in price by 88 percent. NVP dropped the least, only 13 percent over a three-year period.

Table 12: Costs of antiretroviral drugs in Brazil (1996-2000), Generic Antiretroviral Products produced in Brazil

	1996	1997	1998	1999	2000	Price decrease over period
AZT (100mg)	56	53	45	21	18	68%
ddI (100 mg)	1.85	1.39	1.02	.76	.51	72%
3TC (150 mg)	2.90	2.70	2.39	1.51	.83	71%
d4T (40 mg)	-	2.32	1.02	.64	.28	88%
NVP (200 mg)	-	-	3.04	3.02	2.63	13%

In Table 13, the 1996 to 2000 Brazil prices are compared to best global generic ARV prices available in May 2003. From 2000 to May 2003, prices for generic ARVs dropped by an additional 65 percent for AZT, 75 percent for ddI, 89 percent for 3TC, and 86 percent for d4T. For NVP, the change was even greater -- 95 percent.

Table 13: Early Brazil versus Best Global Price for Generic Antiretroviral Drugs

	Brazil 1996	Brazil 1997	Brazil 2000	May 03 Best global price	Decrease from Brazil 2000 generic price	Decrease from Earliest Generic Price
AZT (100mg)	.56	.53	.18	.063	65%	89%
ddI (100 mg)	1.85	1.39	.51	.1275	75%	93%
3TC (150 mg)	2.90	2.70	.83	.09	89%	97%
D4T (40 mg)		2.32	.28	.04	86%	98%
NVP (200 mg)			2.63	.14	95%	95%

Had the 2000 generic prices been used as the benchmarks for this case, the *cost* of NVP would have been estimated at $8.74 per day, far higher than the current BI prices of $1.82 per day (inclusive of VAT). If the 2000 Brazil generic 3TC prices had been used, the *cost* would have been estimated at $2.76 per day, compared to the current GSK price of $3.23 per day. Of course, today more recent generic prices can be used to estimate the BI and GSK *costs*. But over time these estimates may also seem high.

Products such as Efavirenz/Stocrin and Nelfinavir/Viracept are patented in Brazil, and for these and all other ARV products patented after 1996, there is no significant generic market today. For these products, the 166 percent of generic costs formula would not *(now)* justify an excessive pricing charge, even though prices are likely above the cost of efficient generic production, which is feasible should the generic market be opened up for these products. This also leads to the paradox that NVP, a product that faces generic competition in the important Brazil ARV market, would be considered excessive under the formula, while Stocrin *(a product in the same J05AG Non-nucleoside reverse transcriptase inhibitors class as NVP)* would not, even though there is only about an 11 percent difference in price for a daily treatment.