

## **IN THE COMPETITION COMMISSION OF SOUTH AFRICA**

In the complaint submitted by:

**TREATMENT ACTION CAMPAIGN**

Concerning the conduct of:

**MSD (PTY) LTD**

**MERCK & CO., INC. AND RELATED COMPANIES**

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### **LEGAL SUBMISSIONS**

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#### **LEGAL BASIS OF THE COMPLAINT**

1. The complainant alleges that the companies that are the subject of this complaint have abused their dominant positions in the markets for the antiretroviral (“ARV”) medicine efavirenz (“EFV”) by refusing to license other firms to import and/or manufacture generic versions of this medicine on reasonable and non-discriminatory terms. As is the case with the statement of complaint, MSD (Pty) Ltd (“MSD”), Merck & Co. Inc. (“Merck”) and all relevant related companies are referred to collectively as the respondents.
2. In refusing to license on reasonable and non-discriminatory terms, the respondents have – without good cause – threatened access to comprehensive treatment for HIV/AIDS in both public and private sectors, and in so doing have engaged in exclusionary acts where the anti-competitive effects of those acts outweigh their technological, efficiency or other pro-competitive gains, as prohibited by section 8(c) of the Competition Act 89 of 1998 (“the Act”). The precise manner in which the respondents have threatened access to treatment is dealt with in detail in the statement of complaint, which sets out the evidence relied upon by these legal submissions.
3. The complainant alleges that the respondents’ conduct constitutes “economic activity within, or having an effect within, the Republic”, as contemplated by section 3(1) of the

Act. The complainant further alleges that in relation to EFV, the respondents are dominant firms as contemplated by section 7 of the Act. In the result, the prohibition in section 8(c) of Act is applicable. The relevant markets in which dominance is alleged are detailed below.

4. The respondents satisfy the threshold requirements in section 6 of the Act. In the 2006 financial year, the gross revenue of each of the respondents from income in, into or from South Africa, arising from the transactions set out in item 3(1) of the Schedule to the Determination of Threshold in terms of Section 6(1) of the Act, exceeded the threshold of R5 million contained in Government Notice 562 in *Government Gazette* 22128 dated 9 March 2001.

## **STRUCTURE OF THESE LEGAL SUBMISSIONS**

5. These legal submissions cover four matters:
  - a. Establishing dominance;
  - b. Establishing abuse of dominance;
  - c. The manner in which the Competition Commission (“the Commission”) should conduct its investigation; and
  - d. The relief the Commission should pursue in the event that it refers the complaint to the Competition Tribunal (“the Tribunal”) for adjudication.
6. In relation to dominance, these submissions will show that the respondents have more than 45% of the relevant markets, meaning that they are automatically considered by the Act as dominant in the relevant markets.
7. On abuse of dominance, the submissions will address the following:
  - a. Developing an approach to section 8 of the Act –
    - i. within the context of the Act as a whole;
    - ii. in light of the rights entrenched in the Constitution of the Republic of

South Africa, 1996 (“the Constitution”), in particular the right to have access to health care services in section 27 and the corresponding obligations it places on the state regarding its realisation; and

- iii. against the backdrop of regional and international law; and
  - b. Interpreting section 8(c) and applying it to the facts.
8. In considering the manner in which the Commission should conduct its investigation, these submissions will address –
- a. the evidence that the complainant has been unable to secure; and
  - b. the information that lies under the control of the respondents.
9. Finally, in considering relief, these submissions identify the applicable relief provisions in section 58 of the Act that would permit the Tribunal to order the respondents to stop refusing to license on reasonable and non-discriminatory terms.

## **DOMINANCE**

10. The relevant geographical market for the ARV medicine that is the subject of this complaint is the national South African market. This follows from the fact that the registration of and the authorisation to sell and use medicines is conferred on a national basis by the Medicines Control Council (“the MCC”). Other factors supporting such a finding include the national procurement of ARV medicines in terms of the *Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa* (“the Operational Plan”), the national regulation of the medical scheme industry (which is responsible for a significant part of private ARV medicine sales in the country), and the regulation of patent protection that also takes place at the national level.
11. As a result of the respondents’ failure to license any generic company other than Aspen and Adcock, coupled with Aspen’s failure (to date) to secure MCC approval and Adcock having only recently received MCC approval for its 600mg EFV tablet, EFV is not at present sold in the South African market in the form of generics. In other words, the

respondents' branded EFV (Stocrin<sup>®</sup>) is not substitutable by equivalent generic products in South Africa.

12. For the purposes of establishing whether the respondents are dominant in a relevant market, the remaining question is whether other ARV medicines that are available in South Africa can be substituted for the particular medicine that is the subject of this complaint. In other words, can a patient whose proper and effective treatment requires the use of EFV be satisfactorily treated by the substitution of another ARV available in South Africa? This question needs to be addressed both generally and with specific reference to the public sector, where ARV medicine choices are necessarily limited.

### **ARV treatment in the private sector**

13. Even on the assumption that the cost of ARV treatment is not an issue, ARV medicines are generally not substitutable for each other. In order to access optimal ARV treatment, a person living with HIV/AIDS must at a minimum be able to have access to the ARV medicine that is the subject of this complaint. This is because ARV treatment requires the commencement of at least three ARV medicines simultaneously, with alternative regimens being necessary to meet specific requirements at initiation of treatment and to substitute for regimens in the case of unmanageable side effects or treatment failure. This is explained in more detail in Dr Wood's expert affidavit, which is annexed to the statement of complaint as **Annexure RW**.
14. The result is that EFV constitutes its own market both in respect of manufacturers and marketers. Coupled with patent protection and the non-availability of generic equivalents in the market, the international respondents (as manufacturers and suppliers to South Africa) and the South African respondent (as a marketer within South Africa) are dominant in respect of the South African market for the particular ARV that is the subject of this complaint. In this case, therefore, dominance exists regardless of the respondents' share of the market for the particular therapeutic class of ARV medicines of which EFV is a part.

15. In the alternative, it can also be shown that the respondents are dominant firms with respect to the relevant therapeutic class – non-nucleoside reverse transcriptase inhibitors (“NNRTIs”). Our analysis proceeds on the logical assumption that there is no basis for suggesting that, in relation to South Africa, the market share of the manufacturing and/or supplying respondents is significantly different from that of the market share of the marketing respondent.
16. Available information for the period January to December 2006 indicates that MSD was responsible for ± R69.3 million worth of EFV sales, or 68.7% of the NNRTI market. In terms of units sold, MSD was responsible for ± 436 000 units, or 74.6% of the NNRTI market. For the period January to June 2007, MSD sold ± 296 000 units of EFV (80.8% of the NNRTI market) at a cost to consumers of ± R46.3 million (76.5% of the NNRTI market). All of these figures are substantially in excess of the 45% threshold at which the provisions dealing with abuse of dominance are automatically triggered.

### **ARV treatment in the public sector**

17. The public sector, which is responsible for the majority of ARV medicine sales in South Africa, provides ARV treatment in accordance with national treatment guidelines. Wood’s expert affidavit, which discusses the guidelines in some detail, explains why – in addition to the reasons advanced in respect of the private sector – the manner in which ARV treatment is provided in the public sector leads to the conclusion that other ARV medicines cannot ordinarily be considered as substitutable for EFV. But even if therapeutic class were to be deemed to be the relevant market, the respondents remain dominant in the public sector market. This is because a majority of public sector patients on ARV treatment have been prescribed EFV as the NNRTI of choice.

### **Conclusion**

18. In paragraph 12 above, these submissions raised the issue whether other ARV medicines that are available in South Africa can be substituted for the ARV medicine that is the subject of this complaint. In other words, can a patient whose proper and

effective ARV treatment requires the use of EFV be satisfactorily treated by the substitution of another ARV available in South Africa? For the reasons identified above, the answer is clearly no. As there are no generic equivalents available in South Africa of any of the ARV medicines that are the subject of this complaint, the respondents are clearly dominant in their respective markets, whether determined in relation to therapeutic class, sub-class or individual ARV medicine.

## **ABUSE OF DOMINANCE**

19. The question that next arises is whether the respondents' conduct, when viewed in context, constitutes prohibited abuse of dominance as contemplated by section 8(c) of the Act. At the outset, it is important to note that the complainant does not claim that the mere exercise of exclusive rights in a patent in and of itself constitutes prohibited conduct. However, it does submit that under South African law the mere exercise of an exclusive right in a patent does not in and of itself provide justification for refusing – on reasonable and non-discriminatory terms – to license in all circumstances.

### **Developing an approach to section 8 of the Act**

20. These submissions first address section 8 of the Act as a whole before considering how best to interpret section 8(c) and apply it to the facts. As already indicated, section 8 must be considered –
- a. within the context of the Act as a whole;
  - b. in light of the rights entrenched in the Constitution, in particular the right to have access to health care services in section 27 and the corresponding obligations it places on the state regarding its realisation; and
  - c. against the backdrop of regional and international law.

### *Understanding section 8 within the Act as a whole*

21. According to section 2, the Act's purpose "is to promote and maintain competition" in

South Africa so that a range of outcomes are achieved. In other words, the Act is a tool to achieve certain desirable outcomes, including –

- a. “provid[ing] consumers with competitive prices and product choices”;<sup>1</sup> and
- b. “advanc[ing] the social and economic welfare of South Africans”.<sup>2</sup>

22. Sections 1(2) and 1(3) provide some guidance regarding the interpretation of the Act:

- a. Section 1(2) requires that the Act be interpreted “in a manner that is consistent with the *Constitution* and gives effect to the purposes set out in section 2” and “in compliance with the international law obligations of the Republic.”
- b. Section 1(3) permits the consideration of “appropriate foreign and international law” when “interpreting or applying” the Act. Simply put, only foreign or international law that is appropriate may – but need not – be considered in the interpretation and application of the Act. Importantly, such law is not binding.

23. These submissions deal with the Constitution – which recognises rights to life, dignity and access to health care services (including access to medicines) – in some detail below. It is important to note at the outset that these rights are express constitutional entitlements which impose both positive and negative obligations on the state regarding their realisation.

24. In contrast, the constitutional provision dealing with property is somewhat differently framed. There is no positive constitutional right to property other than in respect of “access to land on an equitable basis”. Instead, “[n]o one may be deprived of property except in terms of law of general application”, “no law may permit arbitrary deprivation of property” and “[p]roperty may be expropriated only in terms of law of general application ... for a public purpose or in the public interest” and subject to “just and equitable” compensation. The full import of this is discussed below.

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<sup>1</sup> Section 2(b)

<sup>2</sup> Section 2(c)

25. Section 8 of the Act, which prohibits various forms of conduct that are considered abusive when carried out by dominant firms,<sup>3</sup> essentially prohibits firms from:
- a. charging unreasonably high prices that harm consumers (subsection (a));
  - b. refusing access to essential facilities when economically feasible to do so (subsection (b)); and
  - c. impeding or preventing competitors or potential competitors from entering into or expanding within markets *under certain circumstances* or *in certain ways* (subsections (c) and (d) respectively).
26. When read in light of the purpose of the Act and the provisions regarding its proper interpretation, section 8 must be viewed as playing a strong consumer protection role. This is reinforced by the preamble to the Act, which expressly recognises that “an efficient, competitive economic environment, balancing the interests of workers, owners and consumers and focused on development, will benefit all South Africans.” In other words, the primary purpose behind section 8 is to ensure fair competition as a means of securing the broader public interest.

#### *Impact of the rights entrenched in the Constitution*

27. How then is the broader public interest determined?
28. The Constitution recognises rights to life, dignity and access to medicines,<sup>4</sup> imposing both positive and negative obligations on the state regarding their realisation. Section 39(2) of the Constitution requires “the spirit, purport and objects of the Bill of Rights” to be promoted “[w]hen interpreting any legislation”. In other words, the provisions of a

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<sup>3</sup> It does this together with section 9 of the Act.

<sup>4</sup> This is implicit in the judgment of Chaskalson CJ in *Minister of Health v New Clicks South Africa (Pty) Ltd (Treatment Action Campaign and Another as Amici Curiae)* 2006 (2) SA 311 (CC) at paragraph 314:

“The purpose of section 22G of the Medicines Act read in the context of the Medicines Act as a whole is to enhance the accessibility and affordability of medicines. This is an obligation of the state which in terms of section 27 of the Constitution is obliged to take reasonable measures to enhance access to health care.”

statute must be interpreted to give effect to what those entrenched rights in the Constitution seek to achieve.

29. By contrast, as we have already noted, the Constitution does not recognise a positive constitutional claim to property. The relevant constitutional provision in this regard is negative, namely the prohibition of arbitrary deprivation of property. If one assumes that rights in intellectual property (“IP”) – such as exclusive rights in patents – constitute property as contemplated by section 25 of the Constitution, and further assumes that an order compelling an exclusive rights holder to license constitutes a deprivation of property, section 8 thus does not contemplate the balancing of two positive constitutional rights. It requires a different sort of exercise.
30. What the form and content of the relevant constitutional rights show is that the proper approach to section 8 – which must be interpreted “in a manner that is consistent with the Constitution” – is one which sees it as one of the legislative measures which aim to discharge the state’s positive obligations in respect of the express entitlements – such as ensuring access to medicines – in a manner that does not lead to arbitrary deprivation of property. A deprivation of property is “arbitrary” when the law which authorises it does not provide sufficient reason for the deprivation in question or is procedurally unfair.<sup>5</sup> And so the question will be whether ensuring access to medicines provides sufficient reason for a deprivation or limitation of IP rights.
31. Given that the aim of section 8 is to advance consumer welfare, which in this instance is ensuring access to a sustainable supply of a wide range of affordable EFV products, the question to ask in interpreting and applying the section is whether sufficient reason has been advanced, in the circumstances, for depriving the respondents of their exclusive rights in the IP concerned. In other words, can the respondents justifiably be ordered to license other firms – on reasonable and non-discriminatory terms – to import and/or manufacture generic versions of these medicines in circumstances where –

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<sup>5</sup> *First National Bank of SA Ltd t/a Wesbank v Commissioner, South African Revenue Service and Another; First National Bank of SA Ltd t/a Wesbank v Minister of Finance* 2002 (4) SA 768 (CC)

- a. a refusal to license on such terms results – or has the strong potential to result – in the negative impact on consumer welfare as set out in the statement of complaint;
- b. the respondents are on record stating that they are in any event selling their ARV medicines at cost; and
- c. the respondents appear unlikely to suffer any real harm if they were to be compelled to license?

These submissions answer the question in the affirmative.

### *Regional and international law*

32. The Act draws a distinction between “international law obligations” on the one hand, and “appropriate foreign and international law” on the other. The Act *must* be interpreted in compliance with the former, whereas the latter *may* be considered when the Act is interpreted or applied. In this section, we first deal with South Africa’s international law commitments that are of relevance to section 8 and the facts of this complaint. We then consider non-binding international law. To end this section, we consider an appropriate approach to foreign case law, with the relevant cases being addressed in the next section dealing with section 8(c).

### Relevant international law obligations

33. The following relevant international human rights law instruments are binding on South Africa:
  - a. International Covenant on Civil and Political Rights (“ICCPR”);
  - b. Convention on the Rights of the Child (“CRC”);
  - c. Convention on the Elimination of All Forms of Discrimination against Women (“CEDAW”);
  - d. African Charter on Human and People’s Rights (“ACHPR”); and
  - e. Convention on the Elimination of All Forms of Racial Discrimination (“CERD”).

34. Collectively, they recognise a range of rights that underpin and reinforce the provisions of the Constitution, including:
- a. The right to life (Article 6 of the ICCPR);
  - b. The right to the best or highest attainable standard of health (Article 24 of the CRC and Article 16 of the ACHPR); and
  - c. The right of equal access to health care services (Article 12(2) of CEDAW and Article 5(e)(iv) of CERD).
35. South Africa is also bound by various other international law instruments. Of particular importance to this complaint is the World Trade Organization (“WTO”) Agreement on Trade-related Aspects of Intellectual Property Rights (“TRIPs”), which requires WTO members to respect certain minimum levels of IP protection. Importantly, however, TRIPs does not stand in the way of the approach to section 8 adopted in these legal submissions. If anything, TRIPs provides significant space within which competition law and policy may be interpreted and applied to ensure access to a sustainable supply of affordable medicines.
36. Articles 31(c) and (k) of TRIPs, which respectively deal with the compulsory licensing of semi-conductor technology and conditions upon which licences may generally be ordered in respect of all patented medicines, implicitly recognise that anti-competitive practices involving patents are particularly egregious. Importantly, TRIPs provides no definition of anti-competitive practice, leaving member states with considerable flexibility in this regard.
37. In addition, the WTO’s *Declaration on the TRIPs agreement and public health* (“the Doha Declaration”) recognises that the agreement “does not and should not prevent [WTO] members from taking measures to protect public health”. It further reaffirms “the right of WTO Members to use, to the full, the provisions ... which provide flexibility for this purpose”, asserting that TRIPs “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”.

Non-binding international law

38. Two non-binding international law human rights instruments are of particular relevance:
- a. International Covenant on Economic, Social and Cultural Rights (“ICESCR”); and
  - b. International Guidelines on HIV/AIDS and Human Rights (“the international guidelines”).
39. The ICESCR is not binding on South Africa because, although it has been signed by the Executive, it has yet to be ratified by Parliament. Despite this, the ICESCR and its associated General Comments – which are issued by the United Nations Committee on Economic, Social and Cultural Rights and are aimed at providing interpretive guidance on the ICESCR’s provisions – are relevant to the interpretation of the Constitution (and therefore the Act).<sup>6</sup> This is primarily because the South African Bill of Rights draws heavily on the ICESCR, with section 27 of the Constitution being significantly influenced by Articles 2 and 12 of the ICESCR:
- a. Article 2 of the ICESCR requires that “[e]ach state party ... undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realisation of the rights recognised in the present Covenant.”
  - b. Article 12 of the ICESCR provides that “state parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”
40. In addition, Article 15(1)(b) of the ICESCR provides that everyone has the right “to enjoy

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<sup>6</sup> See *Government of the Republic of South Africa and Others v Grootboom and Others* 2001 (1) SA 46 (CC) at paragraph 45.

the benefits of scientific progress and its applications”.

41. More directly in point are the international guidelines, which were jointly issued by the Office of the High Commissioner for Human Rights and the Joint United Nations Programme on HIV/AIDS in 1998 and revised in 2002. In particular, Revised Guideline 6 of the international guidelines provides as follows:

States should enact legislation to provide for the regulation of HIV-related goods ... so as to ensure ... safe and effective medication at an affordable price ... [and] should also take measures necessary to ensure for all persons, on a sustained and equal basis, the availability and accessibility of ... safe and effective medicines.

#### Developing an approach to foreign case law

42. While foreign case law may provide assistance in understanding how other jurisdictions have addressed the interface between competition and IP law, in particular the circumstances within and the basis upon which holders of exclusive rights in IP may be compelled to license, it must however be approached with caution:
- a. Unlike many other countries, South Africa’s Constitution recognises certain socio-economic rights – relevant in this case is the right to have access to health care services, which includes a right of access to medicines – and imposes positive obligations on the state regarding their realisation; and
  - b. The precise wording of provisions in the competition law of other jurisdictions differs from that of the Act.
43. In considering foreign case law in the context of pharmaceutical products in particular, it is also important to recognise that South Africa faces a significantly greater disease burden – in this case in respect of HIV/AIDS – than all the jurisdictions that are likely to be cited in competition law proceedings in South Africa. These include the United States (“US”), the European Community (“EC”) and Canada.

44. In addition, the existence or otherwise of the South African market for patented medicines has little to no impact whatsoever in creating incentives for the innovator pharmaceutical industry to conduct appropriate research and development (“R&D”):
- a. In countries with comparative advantages based on the ability to conduct pharmaceutical R&D and bring innovative products to markets that are able to bear the cost of expensive new medicines, the balance between competition and IP law must necessarily guard against undermining any incentives to innovate.
  - b. In countries such as South Africa, which ordinarily account for an insignificant fraction of total worldwide profits in respect of innovator pharmaceutical products, no such concern arises.
45. Nevertheless, important principles may still be gleaned from an analysis of foreign case law. Comparative law from the US, the EC and Canada, for example, demonstrates that there is a wide range of acceptable approaches for applying competition law to the holders of exclusive rights in IP, including compelling such holders to license where necessary to meet the public policy interests of competition laws. In all of these jurisdictions, courts and legislatures have adopted varying doctrines and policy frameworks to balance the economic incentives to innovate – which are supposed to be provided by patent laws – with the potential for consumer harm from the anticompetitive effects of the exercise of exclusive rights in the relevant IP.
46. Almost all of the available comparative case law comes from wealthy developed countries, where – as has already been indicated – a particular balance has to be struck between competition law’s demand for competitive markets and patent law’s protection of the right to exclude in order to foster innovation. Even in such jurisdictions, which differ markedly from ours, courts and legislatures have recognised that the right to exclude in patent law is not immune from competition law scrutiny. Where the public interest is clearly better served by compelling the patent holder to profit from its invention through royalties rather than monopoly rents, courts in developed countries have used

the provisions of competition law to compel exclusive rights holders to license in appropriate circumstances.

47. Regarding refusals to license IP in the US and the EC, the key doctrinal debate is not whether but rather the extent to which the various legal doctrines – developed for the regulation of the commercial use of tangible property – can and should apply to the regulation of IP. The argument against such application is essentially that the core purpose of IP is to provide incentives to innovate and invest through the protection of a right to exclude others from the invention. Limiting the right to exclude, it is argued, will harm the core function of IP.
48. In response, supporters of applying the so-called “refusal to deal” doctrines to IP point out that –
  - a. the large majority of IP receives compensation and incentives through licensing, not exclusion; and
  - b. IP is no different in its aims from other forms of property – the goal of protecting a (limited) right to exclude in all private property protection is to provide incentives to invest and innovate, and in exceptional cases a firm can be forced to receive such incentives through royalties and fees rather than exercise of monopoly power.
49. Courts in both the US and EC have concluded that in certain circumstances, it is appropriate to compel holders of exclusive rights in IP to license use of their property to others where the consumer harm from lack of intervention would be severe.
50. The jurisprudence of the European Court of Justice, for example, indicates that competition law principles apply to patented products.<sup>7</sup> While the mere refusal to license cannot in and of itself constitute an abuse of a dominant position,<sup>8</sup> the manner in and circumstances within which an exclusive right in IP is exercised may be considered

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<sup>7</sup> *Parke, Davis & Company v Probel and Others* [1968] CMLR 47

<sup>8</sup> *Volvo AB v Erik Veng (UK) Limited* [1989] 4 CMLR 122

as abusive.<sup>9</sup> In other words, holders of exclusive rights in IP may indeed – in certain “exceptional circumstances” – be compelled to license.

51. In the US, a strong defender of exclusive rights in IP and a country with innovation as one of its competitive advantages, the First and Ninth Circuits (regional federal appellate courts) have adopted standards that presume that a refusal to license IP is based on a legitimate business reason, but allow plaintiffs to rebut that presumption with evidence that the refusal –
- a. blocked all competition with the IP holder in circumstances where licensing would not frustrate the purposes of IP protection;<sup>10</sup> or
  - b. was motivated by anticompetitive animus.

52. Relevant cases that support these findings are addressed in the following section.

### **Interpreting and applying section 8(c) to the facts**

53. In relevant part, section 8(c) provides as follows:

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 ....<sup>11</sup>

54. Section 1(1)(i)(x) of the Act defines an exclusionary act as “an act that impedes or prevents a firm entering into, or expanding within, a market”. A refusal to license, whether absolute or in relation to combinations of ARV medicines including EFV, effectively prevents a firm from bringing any or certain EFV products to market and thus clearly constitutes an exclusionary act. As already shown, the respondents are

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<sup>9</sup> See *Radio Telefis Eireann v Commission of the EC* [1995] ECR I-743 (more commonly referred to “*Magill*”) and *IMS Health GmbH & Co. OHG v. NDC Health GmbH und Co. KG*, [2004] ECR I-5039

<sup>10</sup> A similar conclusion was reached in the opinion of the Advocate-General in *Oscar Bronner GmbH & Co. KG v Mediaprint*, [1998] 4 CMLR 112 at paragraph 62, where he noted that in IP cases, the key inquiry involves the “balancing of the interest in free competition with that of providing an incentive for research and development and for creativity.”

<sup>11</sup> Emphasis in the original

dominant firms. What remains for determination is whether the refusal to license is justified in terms of section 8(c).

55. In many instances, the Act explicitly states which party bears any particular onus and what the nature of that onus is. For example, section 8(d) clearly places the onus on the dominant firm to “show technological, efficiency or other pro-competitive gains”. Section 8(c), however, is silent on onus. Thus what is required is a delicate balancing which results in the determination of the respective “weights” of the anti-competitive impact of the refusal to license, and any “technological, efficiency or other pro-competitive gain[s]”. If the anti-competitive effect outweighs the pro-competitive gains, the exclusionary act is prohibited. If the weight falls in the other direction, it is permitted. In the unlikely event that the weights are identical, then the exclusionary act is not prohibited. Neither party bears any onus in this regard. The adjudicating body is required to determine where the preponderance of the “weight” falls, on the basis of all of the evidence before it.
56. The statement of complaint sets out the evidence that the complainant has been able to obtain. Most of this addresses the anti-competitive effect of the exclusionary conduct. The complainant has however not been able to access much information regarding any possible pro-competitive gains. Other than what is admitted by the respondents in their correspondence with the complainant’s legal representatives (the AIDS Law Project (“the ALP”)), as set out in Jonathan Berger’s affidavit (**Annexure JMB**), any other information relevant to possible pro-competitive gains lies within the exclusive knowledge of the respondents.
57. In the result, these submissions are primarily concerned with the anti-competitive nature of the exclusionary conduct and whether, on the basis of what the respondents have stated to the ALP, such conduct can be justified in the circumstances. The complainant submits that it is entitled to an opportunity to file supplementary papers in response to evidence put forward by the respondents in respect of any pro-competitive gains. As we argue below, the Commission should afford the complainant this opportunity in the event that such evidence is forthcoming. Without access to such information (assuming it

indeed exists), the complainant will be unable to address the “weighing” of the competing considerations.

58. We now address what is contemplated by the term “anti-competitive conduct”, primarily with reference to domestic case law. We then consider whether in the circumstances there is “sufficient reason” to compel the respondents to license on reasonable and non-discriminatory terms. The submissions address the facts that are particular to this complaint, as set out in the statement of complaint, as well as foreign case law. No reference is made to domestic competition law jurisprudence because section 8(c) has yet to be considered in any detail by either the Tribunal or the Competition Appeal Court (“the CAC”).

#### *Defining anti-competitive conduct*

59. In considering the meaning of “anti-competitive effect”, the Tribunal held in *York Timbers Ltd v South African Forestry Company Ltd*<sup>12</sup> that the element of anti-competitive effect required the complainant to demonstrate that the respondent’s “market power has been created or extended in consequence of the alleged act”.<sup>13</sup> On appeal, the CAC upheld the Tribunal’s approach to this issue, holding that the appellant had failed to show the necessary anti-competitive consequences:

[T]he act complained of has not been shown to extend the market power of the respondent qua competition with the appellant.<sup>14</sup>

60. Most recently in *Competition Commission v South African Airways (Pty) Ltd*, the Tribunal engaged in a lengthy discussion of foreign case law on the meaning of anti-competitive effect, arriving at the conclusion that an anti-competitive effect is present if –

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<sup>12</sup> Case No. 15/IR/Feb01

<sup>13</sup> A similar requirement was mentioned in the earlier case of *South African Raisins (Pty) Ltd v SAD Holdings*, Case No. 04/IR/Oct99, where the Tribunal did not require a specific showing of anti-competitive effect under section 8(d) but did note that the conduct was objectionable because it was “applied by a dominant firm to reinforce its dominance” (at paragraph 10). No evidence was discussed in support of this statement.

<sup>14</sup> *York Timbers Ltd v South African Forestry Company Ltd*, Case No. 09/CAC/May01 at paragraphs 8.3–8.4.

- a. there is “evidence of actual harm to consumer welfare”; or
- b. “the exclusionary act is substantial or significant in terms of its effect in foreclosing the market to rivals.”<sup>15</sup>

61. Both, it appears, were regarded by the Tribunal as indications that the conduct “creates, enhances or preserves the market power of the dominant firm”.<sup>16</sup> While injury to, or unfair treatment of, a dominant firm’s rival *per se* is not recognised by the Tribunal as sufficient to demonstrate an anti-competitive effect,<sup>17</sup> the significant or substantial foreclosure of a market to a dominant firm’s rivals will give rise to an inference of anti-competitive effect.<sup>18</sup> For the purposes of this complaint, however, proof of harm to consumer welfare – as set out in the statement of complaint – is sufficient to establish the existence of an anti-competitive effect.

*Establishing “sufficient reason” to compel a firm to license IP*

62. EC case law recognises that, in “exceptional circumstances”, an exclusive rights holder in IP may be compelled to license. In the *Magill* case, the European Court of Justice (“the ECJ”) held that exceptional circumstances may exist in cases where the refusal to license –

- a. prevents the market entry of a new product “for which there is a potential consumer demand”;
- b. cannot objectively be justified; and
- c. results in excluding “competition on a secondary market”.<sup>19</sup>

63. In holding that these three conditions are cumulative, the ICJ in the *IMS* case held that –

<sup>15</sup> Case No. 18/CR/Mar01 at paragraph 132

<sup>16</sup> *Ibid* at paragraph 129

<sup>17</sup> *Msomi v British American Tobacco South Africa (Pty) Ltd*, Case No. 49/IR/Jul02 at paragraph 59

<sup>18</sup> *South African Airways*, above note 15 at paragraphs 128 to 132

<sup>19</sup> *Magill*, above note 9 at paragraph 54

- a. making a new product must be more than “duplicating the goods or services already offered”;
- b. national courts should be left to determine, on the objective facts, whether the refusal to license is justifiable; and
- c. the requirement of a secondary market can be satisfied if “a potential market or even a hypothetical market can be identified”.<sup>20</sup>

64. In so holding, however, the ICJ suggested that the use of IP to block new products coming to market is not the only exceptional circumstance favouring a compulsory licence under EC competition law. In particular it held that –

in order for the refusal [to license] ... to be treated as abusive, it is sufficient that three cumulative conditions be satisfied, namely that that refusal is preventing the emergence of a new product for which there is a potential consumer demand, that it is unjustified and such as to exclude any competition on a secondary market.<sup>21</sup>

65. In an appeal for interim measures against a decision of the EC Commission in *Sun Systems v Microsoft*, the European Court of First Instance (“the ECFI”) noted that –

this case raises the question whether the conditions laid down by the Court in *IMS Health* are necessary or merely sufficient. The Commission contends in the Decision that the existence of exceptional circumstances must be assessed on a case-by-case basis and that it cannot therefore be excluded, without a thorough examination of each case, that a refusal may be abusive, even though the conditions hitherto laid down by the Community judicature are not satisfied.<sup>22</sup>

66. The Commission pursued this line of argument before the ECFI in the main case:<sup>23</sup>

[T]he Commission asserts that, according to the case-law, while undertakings are, as a rule, free to choose their business partners, under certain circumstances a refusal to

<sup>20</sup> *IMS*, above note 9 at paragraph 44

<sup>21</sup> *Ibid* at paragraph 38

<sup>22</sup> 2004 ECR II-04463 at paragraph 206

<sup>23</sup> *Microsoft Corp. v Commission of the European Communities*, Case No. T-201/04 (17 September 2007), available online at [http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=EN&Submit=Rechercher\\$docrequire=alldocs&numaff=T-201/04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100](http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=EN&Submit=Rechercher$docrequire=alldocs&numaff=T-201/04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100), at paragraph 107

supply by an undertaking in a dominant position may constitute an abuse of a dominant position within the meaning of Article 82 EC. ... The Commission maintains that it is entitled to take account of 'exceptional circumstances' other than those identified by the Court of Justice in Joined Cases C-241/91 P and C-242/91 P *RTE and ITP v Commission* [1995] ECR I-743 ('*Magill*') and approved by the Court of Justice Case C-418/01 *IMS Health* [2004] ECR I-5039, but that in any event those exceptional circumstances are present in this case.

67. After analysing relevant case law, the ECFI concluded that –

it is appropriate, first of all, to decide whether the circumstances identified in *Magill* and *IMS Health* ... are also present in this case. Only if it finds that one or more of those circumstances are absent will the Court proceed to assess the particular circumstances invoked by the Commission ....<sup>24</sup>

68. Later in the judgment it held that “the exceptional circumstances identified by the Court of Justice in *Magill* and *IMS Health* ... were also present in this case”. Thus while European competition law remains unclear on this issue, it does strongly suggest that there may well be exceptional circumstances – other than those originally identified in *Magill* – which justify compelling an exclusive rights holder to license IP.

69. EC law is helpful in that it suggests a possible way in which to approach section 8(c). As the statement of complaint shows, the respondents' refusal to license on reasonable and non-discriminatory terms, without good cause, prevents the market entry of new products in respect of which there is potential consumer demand. In other words, in the absence of any compelling justification to the contrary, there is indeed sufficient reason to compel the respondents to license in the circumstances.

70. In addition, EC law is helpful in that it focuses attention on the specific circumstances of any particular case to determine whether compulsory licences should be ordered.<sup>25</sup> In this complaint, the following circumstances make it plain that, in the absence of any

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<sup>24</sup> Ibid at paragraph 336

<sup>25</sup> In particular, consider the reasoning of the ECFI in *Microsoft*, ibid at paragraphs 688 to 712

compelling evidence that suggests otherwise, there is sufficient reason to justify compelling the exclusive rights holders to license their IP:

- a. The refusals to license have caused and will continue to cause consumer harm by threatening access to comprehensive treatment for HIV/AIDS;
- b. By their own admission, the respondents are not making any profit on the sales of EFV products in South Africa; and
- c. The respondents potentially stand to receive royalty payments from multiple licensees in the event that they are compelled to license.

71. Whilst perhaps not as clear as EC law, US law also provides some assistance. In the US, refusals to license are recognised as a subset of the broader refusal to deal doctrine. An analysis of the applicable cases, including those which deal specifically with the refusal to license IP, shows that US law recognises that –

- a. refusals to deal that prevent or stop new products reaching the market may be considered as anti-competitive;<sup>26</sup>
- b. cases involving refusals to license IP should turn on the analysis of whether the refusal to license promotes consumer welfare – “a business justification is valid if it relates directly or indirectly to the enhancement of consumer welfare”,<sup>27</sup> and
- c. a refusal to license could trigger liability where conducted for anti-competitive reasons.<sup>28</sup>

72. Simply put, US law recognises that it is not enough for an exclusive rights holder to justify exclusionary conduct solely on the basis of IP protection. It must be able to show that it has an objectively justifiable basis for refusing to license, one which directly or indirectly promotes consumer welfare. As appears from the correspondence attached to the affidavit of Berger, the respondents have not advanced any such justification in

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<sup>26</sup> *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985)

<sup>27</sup> *Data General Corp. v. Grumman Systems Support Corp.*, 36 F.3d at 1183

<sup>28</sup> *Image Technical Servs. Inc. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997). But see *In re Independent Service Organizations Antitrust Litigation*, 203 F.3d 1322 (Fed. Cir. 2000)

response to the applicant's request that they voluntarily license multiple companies to import and/or manufacture generic EFV products.

73. US and EC case law shows that competition law may even be used to order compulsory licences in countries where the strong protection of exclusive rights in IP may be needed to ensure sufficient incentives to innovate. As already stated, South Africa's context is vastly different. In this case, we are talking about ensuring access to comprehensive treatment in the context of an epidemic that is already responsible for hundreds of thousands of deaths in the country. The respondents appear to have little, if anything, to lose from being compelled to license, whereas the potential of consumer harm caused by the exclusionary conduct is extremely large. In such circumstances, section 8(c) must be interpreted and applied in favour of the complainant.

#### **THE COMMISSION'S INVESTIGATION**

74. As already stated, the complainant has not been able to obtain access to information relevant for the purposes of a thorough investigation of this complaint. In particular, it has been unable to secure comprehensive information relating to allegations of product stockouts and does not have access to information that lies under the control of the respondents. The Commissioner is well placed to obtain this information – using, if necessary, his powers in section 49A of the Act.
75. The complainant is able to provide a list of persons and/or organisations which could be approached by the Commission. It proposes that the Commission seek to obtain all relevant information relating to this complaint from such persons and/or organisations, and, if necessary, advise the Commissioner to summons relevant individuals to furnish such information. In addition, the complainant should be given an opportunity to respond to the defences that the respondents advance. It is only by having an opportunity to reply to the respondents' papers that the complainant will be in a position fully to address the question whether there is sufficient reason to compel the respondents to license on reasonable and non-discriminatory terms.

76. Finally, while the complainant recognises that the Act permits the Commission up to a year to conduct and conclude its investigation, it urges the Commission to do this as a matter of urgency. In particular, this is because the current public sector ARV tender expires in February 2008. While the new tender documents have yet to be published, it is anticipated that this will happen in the near future. If, as the complainant alleges, the respondents are obliged by the Act to license in the circumstances, this would have significant implications for the ARV tender. The complainant therefore requests that the Commission conduct and conclude its investigation as soon as is reasonably possible.

## RELIEF

77. The complainant requests that after investigation, the Commission refer this complaint to the Tribunal in terms of section 50(2)(a) of the Act, with the referral including “all the particulars of the complaint as submitted by the complainant”, in terms of section 50(3)(a)(i). In terms of the provisions of section 58 of the Act, upon a finding that section 8(c) has been violated the Tribunal may “make an appropriate order”, including—

- a. “interdicting any *prohibited practice*”;<sup>29</sup>
- b. “imposing an administrative penalty” in the case of repeat conduct;<sup>30</sup> and
- c. “declaring conduct ... to be a prohibited practice”.<sup>31</sup>

78. The complainant requests that upon referral, the Commission recommend that the Tribunal make orders in terms of all of the provisions referred to in the previous paragraph. In short, this would have the result of the Tribunal –

- a. ordering the respondents to stop refusing to license, effectively compelling them to license on reasonable and non-discriminatory terms; and
- b. declaring the conduct to be a prohibited practice to facilitate damages claims by all persons who can establish that they have suffered loss or damage as a result of the prohibitive practice concerned.<sup>32</sup>

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<sup>29</sup> Section 58(1)(a)(i)

<sup>30</sup> Section 58(1)(a)(iii)

79. As set out in the statement of complaint, the TAC and its allies have engaged in a sustained campaign for many years to ensure that the respondents grant non-exclusive voluntary licenses on reasonable and non-discriminatory terms. The failure of the respondents to act timeously is to be regretted, but can be addressed, even at this late stage, to avert any future damage. Any relief must take these factors into account.

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<sup>31</sup> Section 58(1)(a)(v)

<sup>32</sup> Section 58(1)(a)(v) read with section 65