

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

AFFIDAVIT OF JONATHAN BERGER

I, the undersigned

JONATHAN MICHAEL BERGER

do hereby solemnly affirm:

1. I am employed as a senior researcher and policy, research & communications manager at the AIDS Law Project (“the ALP”), the legal representatives of the Treatment Action Campaign (“the TAC”) – the complainant – in this matter.
2. The facts contained herein are true and correct and within my knowledge, unless the context indicates otherwise.
3. I have read the statement of complaint, and insofar as it pertains to me, confirm its contents.
4. I can be contacted on 011 356 4100 or bergerj@alp.org.za should the Competition Commission (“the Commission”) wish to obtain further information from me.

Purpose of this affidavit

5. This affidavit addresses two issues:
 - a. First, it sets out the ALP's correspondence with MSD (Pty) Ltd ("MSD") regarding the need for the respondents to license companies to import and/or manufacture generic efavirenz ("EFV") products; and
 - b. Second, it addresses stock shortages of EFV in South Africa.

Correspondence with MSD

6. The ALP's first letter to MSD, dated 14 May 2002 and written on behalf of the complainant, called for a meeting to discuss ways to facilitate better access to antiretroviral ("ARV") treatment and the possibility of MSD granting non-exclusive voluntary licences for EFV. This letter is attached as **Annexure JMB1**.
7. In its response dated 29 May 2002 (**Annexure JMB2**), MSD agreed to meet the ALP and the TAC to discuss improving access to HIV treatment in South Africa.
8. After a meeting held on 10 June 2002, the following correspondence passed between the ALP and MSD:
 - a. MSD letter dated 19 June 2002 (**Annexure JMB3**) setting out MSD's position on granting voluntary licences – as discussed at the meeting on 10 June 2002 – and reiterating its commitment to expanding access to ARV treatment;
 - b. ALP letter dated 24 June 2002 (**Annexure JMB4**) providing information to MSD on generic price offers for EFV and indinavir, and calling upon MSD to offer voluntary licenses on reasonable terms for the importation and/or local production of bioequivalent generic products; and
 - c. MSD letter dated 27 June 2002 (**Annexure JMB5**) acknowledging receipt of the ALP letter dated 24 June 2002, and stating that MSD was willing to consider bona fide requests by prospective licensees for voluntary licenses.

9. No further correspondence passed between the parties until approximately 20 months later. In a letter to MSD dated 13 February 2004 (**Annexure JMB6**), the ALP thanked MSD for various meetings. The letter referred to previous correspondence and reiterated the earlier call for MSD publicly to commit to the grant of non-exclusive voluntary licences on reasonable terms for the local production and/or importation of ARV medicines.
10. Following the resumption of correspondence between the parties, the following letters were exchanged:
 - a. MSD letter dated 16 February 2004 (**Annexure JMB7**) acknowledging receipt of the ALP letter dated 13 February 2004, and stating that MSD will publicly reiterate its commitment and licensing strategy in respect of its ARV medicines before 20 February 2004;
 - b. MSD letter dated 20 February 2004 (**Annexure JMB8**) informing the ALP and TAC of a public announcement on MSD's commitment to the South African community and its licensing of ARV medicines, including EFV;
 - c. ALP letter dated 25 February 2004 (**Annexure JMB9**) acknowledging receipt of MSD's public announcement dated 20 February 2004, stating that its contents included a vague reiteration of the intention to consider the granting of voluntary licenses on unknown terms and conditions, and expressly stating that this did not provide a solution to the problem of ensuring access to sustainable supplies of affordable ARV medicines; and
 - d. MSD letter dated 5 April 2004 (**Annexure JMB10**) attaching a public announcement on MSD's intention to grant a licence in respect of EFV to Thembalami Pharmaceuticals ("Thembalami"), and indicating that the announcement would be released the following day.
11. Some seven months later, correspondence between the parties resumed. In a letter dated 15 November 2004 (**Annexure JMB11**), the ALP raised the TAC's concern over MSD's inability to satisfy public sector demand for EFV. Referring to previous

correspondence regarding the call for the granting of multiple voluntary licenses in respect of essential HIV medicines, the letter noted the failure of Thembalami to bring any EFV products to the market.

12. This letter gave rise to the following correspondence between the parties:
 - a. MSD letter dated 25 November 2004 (**Annexure JMB12**) responding to the ALP letter dated 15 November 2004, explaining MSD's decision to grant Thembalami a royalty free licence to manufacture EFV in South Africa, and assuring that MSD was continuing to screen bona fide applications for licences;
 - b. ALP letter dated 6 December 2004 (**Annexure JMB13**) calling on MSD to explain why it has only granted a single licence (to Thembalami), requesting that multiple voluntary licences be granted, and informing MSD that if it did not publicly commit to doing so the TAC would take legal steps to ensure MSD is compelled to license other generic drug companies; and
 - c. MSD letter dated 10 January 2005 (**Annexure JMB14**) stating that MSD was reviewing prospective applicants for EFV licences and intended to license more than a single licensee in South Africa.

13. The correspondence resumed two months later when the ALP sent a letter on 9 March 2005 (**Annexure JMB15**) once again referring to previous correspondence and reiterating the TAC's demands. The letter, which called upon MSD to accede to the TAC's demand to grant multiple licences for the manufacture and/or import of generic EFV products, gave rise to the following correspondence:
 - a. MSD letter dated 1 April 2005 (**Annexure JMB16**) stating that its chief executive officer ("CEO") had been traveling for the previous few weeks but was working on a formal response to the ALP letter dated 9 March 2005;
 - b. ALP letter dated 28 April 2005 (**Annexure JMB17**) reminding MSD's CEO that his formal response was still outstanding; and

- c. MSD letter dated 10 June 2005 (**Annexure JMB18**) requesting a meeting ten days later to discuss MSD's plans to meet the increasing demand for EFV in South Africa.
14. The latest period of correspondence between the parties resumed almost two years later (on 21 May 2007) when the ALP sent a letter to MSD (**Annexure JMB19**) recording the discussion at a meeting between the parties held on 13 April 2007. In that letter, the ALP reaffirmed the demand that MSD grant multiple licences in respect of EFV on reasonable terms, failing which a complaint would be filed with the Commission.
15. This letter gave rise to two further letters between the parties:
 - a. MSD letter dated 30 May 2007 (**Annexure JMB20**) reiterating that MSD was negotiating additional licences for the manufacture and distribution of EFV in South Africa, stating that it was unaware of any interruptions of EFV supply, and stating that should a complaint be filed with the Commission, MSD would defend itself "as appropriate"; and
 - b. ALP letter dated 4 June 2007 (**Annexure JMB21**) informing MSD that the ALP's and TAC's concerns had not been adequately addressed and that a complaint would be filed with the Commission within the following three months if appropriate action was not taken by MSD.
16. Since then, the ALP and MSD have remained in contact:
 - a. On 31 August 2007, MSD sent the ALP a copy of its press release regarding the grant of a voluntary licence to Adcock Ingram Limited (**Annexure JMB22**);
 - b. In early September 2007, the ALP and MSD discussed the possibility of a further meeting – initially requested by MSD – through a series of e-mails and telephone calls;
 - c. An ALP letter dated 18 September 2007 (**Annexure JMB23**) proposed "that the parties meet ... to give ... [MSD] an opportunity to respond to ... [the TAC's]

demands regarding the granting – on reasonable terms – of multiple licences in respect of efavirenz products”; and

- d. Further telephonic and e-mail contact was necessary to finalise a date for the proposed meeting.

17. Unfortunately, the meeting held on 19 October 2007 was unable to resolve the TAC’s concerns.

Shortages of EFV

18. In addition to the EFV shortages discussed in the ALP letter dated 15 November 2004 and referred to in paragraph 11 above, in which the ALP raised the TAC’s concerns regarding MSD’s inability to satisfy public sector demand for EFV, I am also aware of MSD’s run on stock of EFV 50mg in January 2004. The detail of this stock shortage is set out in a TAC letter to MSD dated 19 January 2004 (**Annexure JMB24**) and is also referred to in the ALP letter dated 15 November 2004.
19. I am also aware of other instances regarding EFV shortages. I have been advised that these examples are addressed in Fatima Hassan’s affidavit.

JONATHAN MICHAEL BERGER

SIGNED AND AFFIRMED BEFORE ME AT JOHANNESBURG ON THIS THE 5TH DAY OF NOVEMBER 2007, THE DEPONENT HAVING STATED THAT HE KNOWS AND UNDERSTANDS THE CONTENTS OF THIS AFFIDAVIT, THAT HE HAS CONSCIENTIOUS OBJECTIONS TO TAKING THE OATH, THAT HE HAS NO OBJECTION TO MAKING THE SOLEMN AFFIRMATION AND THAT HE CONSIDERS THE SAME AS BINDING ON HIS CONSCIENCE.

COMMISSIONER OF OATHS