

**IN THE HIGH COURT OF SOUTH AFRICA
(CAPE OF GOOD HOPE PROVINCIAL DIVISION)**

CASE NO: 12156/05

In the matter between

TREATMENT ACTION CAMPAIGN and ANOTHER

Applicants

and

MATTHIAS RATH and OTHERS

Respondents

APPLICANTS' NOTES FOR ORAL ARGUMENT IN REPLY

THE MEANING OF "SELL"

1. In Raats-Rontgen Kriegler AJA explained at page 257 (bundle page 7) that there are five categories of activities which fall within the definition of "sell" in the Medicines Act. They are the following:
 - 1.1 *"sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale";*
 - 1.2 *"authorise, direct or allow a sale";*

- 1.3 *“prepare or possess for purposes of sale”;*
 - 1.4 *“barter or exchange”;* and
 - 1.5 *“supply or dispose of to any person whether for a consideration or otherwise”.*
2. Kriegler AJA refers (at 263G – Bundle page 7) to *“the concluding words ‘for a consideration or otherwise’ which qualify the words ‘supply or dispose of’”*. As he points out, *“...neither barter nor exchange can notionally be imagined without a consideration; hence the qualifying words can only refer to the two activities immediately preceding them, namely “supply” and “dispose of””*.
 3. The submission that the words *“for consideration or otherwise”* apply to barter is therefore quite wrong. The Appellate Division has held to the contrary.
 4. If one asks the meaning of the phrase *“supply or dispose of ... whether for a consideration or otherwise”* then it plainly includes a donation. The words *“or otherwise”* can only have that meaning.
 5. It follows that a donation is a sale in terms of the Act.

6. This follows plainly from the clear wording of the section. The conclusion is unavoidable. There are also at least two good policy reasons why the term sale is given an extended meaning which includes donation.
7. First, the main purpose of the Act is to protect members of the public against “quackery”. If a person is given a harmful or useless substance and told that it will cure cancer, then harm is done to that person, whether or not he or she paid for it. Using a harmful substance will itself cause harm. Using a substance which is useless or ineffective, instead of an effective substance, will also lead to harm. The protection of the public would therefore be undermined if the Act applied only to sale for a consideration or for a profit.
8. Secondly, the giving away of free products is a well known means of creating a market, and particularly in relation to medicines. Dr Rath relies on the book The Truth About Drug Companies by Dr Marcia Angell. He attaches it as an annexure to his affidavit (annexure “**MWR9**”). This is what Dr Angell says about the provisions of free medicines (at page 115):

“In 2001, drug companies gave doctors nearly \$11 billion worth of “free samples”. They were almost always the newest, most expensive me-too drugs. The companies knew that when the free samples ran out, you and your doctor would be hooked on them. The drugs weren’t really free, of course. The costs were simply added on to drug prices (these firms are not charities)”.

9. It is correct that there is not any evidence that Dr Rath has sold any of his products in South Africa for a consideration. That however, is irrelevant, as the definition of “sell” includes donation.

10. Paragraph 59.8 of the founding affidavit of Mr Geffen refers to an advertisement from Dr Rath’s site on the internet, which is attached as “**NG15**”. The internet site is <http://store/dr/rath/vitamins.com>. Annexure “**NG15**” is at page 355 (see also “**ALG3**” at page 354). It shows that VitaCore Plus and the other substances (excluding VitaCell) which are the subject matter of this application are being sold by Dr Rath on the internet.

11. In the final analysis, though, it does not matter whether Dr Rath is a philanthropist or a very shrewd businessman building a market. Whichever it is, he must carry out his activities within the law. The law prohibits the sale (which includes donation) of medicines which are required to be registered, unless they have been registered.

THE MEANING OF “MEDICINE”

12. It is trite that the meaning of “*medicine*” is potentially very wide if it is read literally. It has to be read sensibly within its context. At the heart of the definition is that it is a substance which is used or purports to be suitable for use or is manufactured or sold for use for one of the defined purposes. The defined purposes, broadly speaking, are the diagnosis or treatment or mitigation or prevention of disease or its symptoms.
13. If the question is then asked “*Who decides what is a medicine?*”, then the answer is that the Legislature has decided what is a medicine. It has defined it, and it has not (despite what Mr Mseleku believes) given the MCC the power to determine what is a medicine.
14. If a dispute arises as to whether a substance is a medicine, then the only body which can determine that dispute is a Court, which has to decide whether it falls within the definition given by the Legislature.
15. So when does a substance “purport to be suitable for use” for one of the indicated purposes? A substance can not speak. Someone has to ‘purport’ it that it is useful for one of the two purposes. There are various ways in which that can happen. One of the ways is in writing, thought the label or package insert. However, that is not the only way in which it can happen. If a person makes claims that a substance is suitable for use for

the treatment or mitigation or prevention of disease, and distributes it on that basis, and subsequently claims that it has been effective in achieving the desired goals, then that substance is a medicine for the purposes of the Act. That is what the Rath Respondents have done. They have consistently advertised that the vitamins which they have donated have cured people of AIDS. The Second Respondent's newsletter FV14 (pages 270 – 281), is a clear example of this. It states that Dr Rath has donated a vitamin programme to HIV positive people "*to improve their health*"; it refers to "*the vitamins donated by the Dr Rath Health Foundation*"; and it includes testimonials by persons who state that as a result of taking vitamins, they have been cured of HIV/AIDS.

16. It is difficult to think of a clearer example of a "*medicine*" within the meaning of the Act: it is a substance which has been used and purports to be suitable and is sold (in the extended sense) for the defined purposes, namely for the treatment, mitigation, or prevention of disease or its symptoms. There are multiple examples of this in the papers, which are referred to in our heads of argument from paragraph 78 to paragraph 87.
17. In any event, the evidence is clear that the Rath products are used and sold for use for the defined purposes. The whole basis of Dr Rath's affidavit is that they achieve those purposes. That is the purpose for which they are manufactured and distributed. There is no other purpose.

That means that they are a medicine, whether or not they “purport” to be suitable for this purpose.

18. That these substances are used or purport to be suitable for use or are manufactured or sold for use for the defined “*medical*” purposes is in Dr Rath’s affidavit. At paragraph 294 (page 2919), he states that:

“(a) The most important findings of this micronutrient programme in Khayelitsha were: micronutrient supplementation in people affected by AIDS was associated with a statistically significant decrease of all “AIDS defining symptoms” as classified by the WHO [World Health Organisation] definition of Bangui ...

(b) In addition to the improvement of these symptoms with micronutrient supplementation a significant decrease in fungal and other opportunistic infections was also observed.

(c) Moreover, during the micronutrients programme other AIDS related symptoms also improved including, sores, colds, nausea, fatigue, depression, headache, skin rashes, swollen glands, joint pain and numbness in the extremities”.

19. It is hard to find a clearer statement that the substances were used or purported to be suitable for use or were sold for use in the treatment or

modification or prevention of disease or the symptoms thereof. That makes them medicines. The core substance used, on Dr Rath's own version was his product VitaCell. It is not registered as a medicine.

THE LINK BETWEEN THE CLAIMS AND THE DISTRIBUTION OF THE PRODUCTS

20. The Rath Respondents assert that they are carrying on two entirely unrelated activities:

20.1 On the one hand, they are promoting their views on the value of vitamins in "*reversing the course of AIDS*" as part of a participation in public debate; and

20.2 On the other hand, in an entirely unrelated activity, they are distributing vitamin products (including VitaCell) as part of a community health programme, which has nothing to do with the claims in respect of AIDS.

21. This does not stand up to scrutiny, for two reasons.

22. First, if I publish advertisements in the newspapers and elsewhere stating that vitamins cure cancer, and I also run a shop in which I sell substances which I identify as vitamins, then there is obviously the clearest possible link between the advertising and the sale. The advertising is intended to create the demand, and the demand will lead customers naturally to my

products. It will not avail me to say that the brand names of my products were not mentioned in the advertisements. The advertisement is clearly aimed at persuading readers that vitamins are a cure for cancer, and it will follow naturally that the demand for my products will be increased. This is what happened in this case. The Rath Respondents distributed pamphlets in Khayelitsha stating that vitamins reverse the course of AIDS. In Khayelitsha, a clinic was conducted in which their vitamin products were distributed, *inter alia*, to people with AIDS. To suggest that these activities are unrelated simply flies in the face of the facts. It matters not whether or not the advertisements referred to the specific brand names.

23. Secondly, Dr Rath himself made this link quite clear to any “patients” who might have missed it. Annexure “**MWR123**” to his affidavit (pages 5393 – 5396), is styled an information sheet. It makes the following claims:

24. Dr Rath says the following of this pamphlet:

“Every person who decided to participate in the vitamin programme received the following documents:

(ii) An information sheet explaining the details of this community health programme (“MWR123”), detailing the following facts:

1. The responsibility of SANCO for this programme.

2. *The vitamins being donated by the Dr Rath Foundation.*
 3. *And other details as shown in the annexure”.*
25. The link between the claims and the products distributed, could not be clearer: the claims are made in writing to every person who participates in the programme and receives the vitamins.
26. We submit that this is really the end of the matter as far as that issue is concerned. The Rath Respondents themselves, quite deliberately, link these claims to their products which are distributed to the “participants” . .
27. The same link is made in annexure “**FV14**” (pages 270 – 281). This is a “*community newsletter*” distributed by the Dr Rath Health Foundation Africa. It states that in Khayelitsha “*a nutritional programme for HIV positive patients with advanced AIDS was conducted. None of the patients was taking any ARV drugs. The goal of this programme was to show that a combination of vitamins and other micronutrients can improve immune system function and quality of life for AIDS patients*”. [The reference to “*patients*” is revealing in the light of the claim now made that this is simply a community vitamin programme]. It states further (page 271):

“And the nutritional programme conducted by the South African National Civics Organisation (SANCO) in Khayelitsha and Gugulethu has proved that with micronutrients alone – you can reverse the course of AIDS”.

“In addition to the vitamins donated by the Dr Rath Health Foundation to the people of South Africa is knowledge about the importance of vitamins and other micronutrients in keeping our bodies healthy and preventing unnecessary infections”.

28. The link between the claims and the substances which are distributed by Dr Rath (whether or not through the agency of SANCO) could hardly be clearer.
29. To put the matter beyond any doubt as to what is being distributed through this programme, one need only quote what Dr Rath says (paragraph 278, page 2911):
 - 29.1 Potential *“patients”* (in his own words) are given a pamphlet extolling the virtues of vitamins in reversing the course of AIDS;
 - 29.2 Vitamins are then distributed to these *“patients”*; and
 - 29.3 The product which is distributed is VitaCell, which contains vitamins.

THE CALL UP NOTICE

30. It appears that the Respondents now do not dispute that the call up notice is a notice requiring the registration of the medicines which are listed therein. This could hardly be disputed: on its own terms and in its words, it is a call up notice issued in terms of section 14(1) of the Medicines Act, together with a resolution in terms of section 14(2) of the Act, requiring the registration of the substances listed therein. The only powers in sections 14(1) and 14(2) are to call up medicines for registration.
31. Faced with this obvious difficulty, the Rath Respondents come up with the following explanations as to why their products are nevertheless not governed by the notice:
- 31.1 The notice will have lapsed within six months. This however, is not correct. What the notice (page 803) states is that a six month period is allowed for submitting products for registration. It says nothing about the notice lapsing within six months, and indeed it would be nonsensical if it did so. One cannot imagine any reason why medicines would be required to be registered only for a period of six months, and those producers who decided not to register their medicines, could simply ignore the notice.
- 31.2 It has not been proved that VitaCell was available for sale in South Africa at the time of the notice (2002). But this is irrelevant. The

notice states in terms (page 803) that it relates to *“medicines available for sale or distribution in the Republic on the date on which it comes into operation and shall relate also to medicines that become available after the said date”*.

- 31.3 Then it is said that there is no resolution which states that VitaCell is subject to registration. That is, of course, true insofar as the notice does not refer to that particular product. It does not refer to any particular products at all. What the notice requires is the registration of *“nutritional substances that purport to have therapeutic or medicinal effects”*. VitaCell falls within that category of medicines, and therefore falls within the category of medicines that are required to be registered.
32. It follows inexorably that VitaCell is required to be registered as a medicine. It is common cause that it has not been registered.

SCHEDULED SUBSTANCES

33. It is common cause that:

33.1 VitaCell contains N-acetylcysteine (NAC).

33.2 NAC is a substance listed in Schedule 2 to the Medicines Act.

- 33.3 VitaCell is being distributed by the Dr Rath Foundation either to SANCO (the version of the Rath Respondents) or directly to the patients in the clinics (the Applicants' version).
34. Section 22A(5) of the Medicines Act provides that a Schedule 2 substance shall not be sold [which has the same extended meaning including donated] by any person other than a pharmacist; pharmacist's intern; pharmacist's assistant; manufacturer or wholesaler for sale to a person who may lawfully possess it; or various health professionals subject to certain limitations (eg licensing).
35. Section 25(6) provides that a sale under section 22A(5) shall only take place on condition that all the prescribed particulars of every sale are recorded in the prescribed manner in a prescription book or other permanent record; an authorised prescriber who has given verbal instructions to a pharmacist shall within 7 days provide a written prescription; a seller shall retain the prescription or order for a period of not less than 5 years from the date of sale; and various other limitations.
36. According to the Rath Respondents, they have donated VitaCell to SANCO, which then distributes it. A vague claim is made that there are medical practitioners involved. However, it is striking in this regard that:
- 36.1 no single medical practitioner has been identified by name;

- 36.2 no medical practitioner who allegedly dispenses these medicines has made an affidavit stating that he or she does so at the Khayelitsha Clinic;
- 36.3 it is not alleged that the medical practitioners are licensed to sell these products;
- 36.4 even SANCO itself has not made an affidavit claiming that it distributes the medicines in an authorised fashion. All that has been placed before the Court is the affidavits of some lay people who went to the clinic, and who say that they thought that they were dealing with SANCO;
- 36.5 there is no suggestion, let alone any evidence, that any of the prescribed records have been kept or that the other prescribed conditions have been fulfilled.
37. Under the circumstances, the conclusion is inescapable that VitaCell, containing a Schedule 2 substance, is being distributed in a manner inconsistent with the requirements of section 22A of the Act. That is an offence. It matters not whether the products are distributed directly through Dr Rath's organisation through SANCO. On either basis, the Rath Respondents are selling (in the extended sense) the medicines for distribution in an unlawful manner. They are not entitled to distribute these substances either to their "patients" or to SANCO.

38. In oral argument, counsel for the Rath Respondents did not suggest that the distribution was in accordance with the requirements of section 22A of the Act. Rather, they contended that the Rath Respondents were not obliged to comply with section 22A of the Act, because VitaCell is exempt from the provisions of section 22A by virtue of sub-paragraph (a) to Schedule 2, which states that a scheduled substance is excluded when *“specifically packed, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products, which have no pharmacological action or medicinal purpose”*.
39. This exemption plainly does not assist the Rath Respondents at all:
- 39.1 The NAC is not specifically packed and labelled; and
- 39.2 It is not used for industrial purposes.
40. Plainly, distributing a medicine or even a vitamin product to people in order to improve their health is not an industrial purpose in the usual sense of that term. Again, the Act provides an extended meaning: industrial purpose includes *“the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose”*. The distribution of VitaCell containing NAC does not fall within this extended definition because it is not:

- 40.1 distributed for the manufacture or compounding of any items at all:
it is distributed in an already manufactured item; and
- 40.2 the substance in which it is distributed is plainly intended to have a pharmacological action or medicinal purpose: it is intended to make people well. That after all is the very foundation of Dr Rath's case. He says that NAC makes people well. He says the following of NAC:

“The health benefits of this biological substance are widely documented in the scientific and medical literature. Most significantly, NAC ... has been shown to inhibit the replication of HIV ... The amino acid Cysteine and its biological derivative NAC have properties as antioxidants. NAC has been used in studies to prevent oxidative damage in the liver caused by chemicals, including many pharmaceutical drugs ... The liver detoxifying properties of NAC are particularly noteworthy in the context of this application ...”.

(Paragraph 394(b)-(d), pages 2964 – 2965).

41. The very reason why NAC is included in VitaCell is because Dr Rath believes that it has positive pharmacological or medicinal consequences.

That being so, he can hardly claim that VitaCell is a consumer item or product which has no pharmacological action or medicinal purpose.

42. It follows that it has been shown that the Rath Respondents are selling (in the extended sense) a product containing a scheduled substance, under conditions prohibited by the Medicines Act. This is so whether or not NAC or VitaCell is a medicine: the prohibition is on the distribution of these substances except under the circumstances prescribed by the Act: see sec 22A(1).
43. Dr Rath claims that VitaCell is freely available in the Republic. He produces no evidence to support this assertion. But even if it is true, it takes the matter no further. As a matter of law, scheduled substances may only be distributed in accordance with the prescriptions of the Medicines Act. Whoever does so outside those prescriptions, including Dr Rath, commits an offence.
44. As we have stated, there is no evidence that the Rath Respondents are donating the medicines to qualified medical practitioners. On their version, they are donating it to SANCO, which is plainly not a qualified person under the Medicines Act. But even if on some or other basis it could be said that the donation was a donation to the (alleged and unidentified) medical personnel at the clinics, that would not avail the Rath Respondents. In that event, they would fall foul of section 18B of the Medicines Act, which provides that no person shall "*sample*" any

medicine, and then states in section 18B(2) that for the purposes of this section “*sample*” means “*the free supply of medicines by a manufacturer or wholesaler or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act*”.

45. The reason for this prohibition is plainly to stop the undesirable practice described by Dr Angell, namely the distribution of “*free*” medicines to doctors in order to create a market.

THE “*PERMISSION*” TO DISTRIBUTE VITACELL AS A “*FOODSTUFF*”

46. As we have pointed out in our heads of argument, if a substance is a medicine, then by definition it cannot be a foodstuff. That legal fact cannot be avoided by a person in the Department of Health issuing a letter stating that it is a foodstuff and not a medicine. There is no such power. That contention seems finally to have been abandoned by all of the Respondents.
47. It is striking, however, that the product for which “*permission*” was given by the Foodstuffs section of the Department of Health is not the same product as that which is distributed by the Rath Respondents. The product which “*will be regarded as a nutritional supplement*” is set out in annexure “**MWR1**” (pages 3052 – 3053). The content of the product distributed in Khayelitsha as described on its own label, is set out in the

affidavit of Mr Gray (pages 333 – 334). The contents of these two products differ substantially. In most cases, the VitaCell label lists ingredients at least double the level at which they are listed in the Department of Health's letter. Perhaps most significantly for the purposes of this case, NAC is listed at 15mg in the Department of Health's letter and 30mg in the label of the product actually distributed. The product which is being distributed is plainly not the same product as that which the Department of Health stated would be "*regarded as*" a nutritional supplement, even though it has the same name (VitaCell).

ASSESSING WHETHER ANY RELIANCE CAN BE PLACED ON THE WITNESSES

48. In assessing whether any reliance can be placed on the witnesses, and particularly where they purport to give expert evidence, regard must be had to:

48.1 whether they meet the fundamental requirement of independence: for without independence, they cannot be expert witnesses as at all;

48.2 whether the manner in which they give their evidence is such that they can be regarded as objective;

48.3 the quality of their evidence; and

- 48.4 whether there is reason to doubt their honesty.
49. Dr Rath fails the test on all counts:
- 49.1 He is patently not an independent person: he is personally the First Respondent, and he is the head of the Second Respondent, which in truth is his *alter ego*. Even if no criticism could be made of the quality of his evidence, he could not conceivably qualify as an expert witness. He does not have the necessary measure of independence.
- 49.2 Professor Rollins shows that Dr Rath consistently misrepresents or misunderstands the studies to which he refers. He consistently fails to refer to studies which contradict his own views, in order to explain or distinguish them. He says that studies have conclusions when in fact they show the opposite. He suppresses all reference to the evidence which is hostile to his thesis. All of these are the hallmarks of a person who cannot be relied upon as an expert witness.
- 49.3 His qualities generally show that he is not an impartial person on whom reliance can be made. No person who can publish a book claiming that his work is "*the greatest study ever conducted on planet Earth*" can ask to be taken seriously as an impartial and

disinterested person on whose statements any reliance can be placed where they are in dispute.

49.4 He is on his own showing not an honest person. In this regard one need look no further than his repeated and wilful misrepresentation of what this Court decided in the interdict case. He repeatedly made dishonest statements that this Court had found what it had not found, even to the extent of stating that the Court had found the opposite of what it in fact found. His belated attempt in these proceedings to avoid liability for the clinical trials, for which he claimed authorship in publications all over South Africa and in the international media, again shows that he is not an honest person. His counsel complained in argument that his credibility should have been attacked in the founding papers. With due respect, this complaint is difficult to understand. A person bringing an application cannot be required to anticipate who the witnesses for the respondents will be, what their evidence will be, and to say that their evidence cannot be relied upon. In the nature of things, it can only be done in reply. This is what always happens in motion proceedings. If Dr Rath had had some explanation for his extraordinary conduct in his misrepresentation of the judgment of this Court, in his belated denial of responsibility for the trials, and in the false explanation given in the condonation proceedings, he could have applied for leave to file a fourth set of affidavits. He did

not do so. Certainly, the Applicants can hardly be criticised for dealing with his evidence and his credibility once he had made it an issue in his answering affidavit. They could not have done so earlier.

50. Counsel for the Rath Respondents raises the question whether one can make a finding in motion proceedings either that a witness' expert evidence should not be relied upon, or that the witness is dishonest. The short answer to this is that:

50.1 If it is shown in the affidavits that a witness does not meet the requirements of an expert witness, then a Court can and will make a finding to that effect.

50.2 If the evidence shows that a witness is dishonest, than a Court can and will make a finding to this effect. That happens regularly in the Courts.

51. Dr Niedwicki says very little in her affidavit, if anything, which is relevant to the matters which this Court is required to decide. She too cannot meet the first test for an expert witness, namely independence, in that:

51.1 she is herself one of the Respondents in this case;

51.2 she is a senior staff member and employee of the Second Respondent.

52. Dr Jariwalla:

- 52.1 similarly fails to pass the first hurdle, as he is an employee of the Dr Rath Health Foundation – a matter which he curiously does not disclose in his affidavit, but which is disclosed in passing by Dr Rath;
- 52.2 as is shown by Professor Rollins in his analysis of Dr Jariwalla's affidavit, the latter misrepresents certain of the studies on which he relies; does not refer to the studies which contradict his views; and makes a claim which is in fact not borne out by any of the studies on which he relies, even if they say what he claims they say.
53. Again, Dr Marcia Angell (a person on whom the Rath Respondents and Dr Rath himself particularly rely as an authority who can be trusted) shows why particularly in a matter involving the assessment of medicines, the views of the producers of those medicines cannot be relied upon as impartial: this is what she says:

“No-one should rely on a business for impartial evaluation of a product it sells”. (Page 135)

and:

“We need to end the fiction that big pharma provides medical education. Drug companies are in the business to sell drugs.

Period. They are exactly the wrong people to evaluate the products they sell. I am not saying that all of the information drug companies provide to doctors is false. Some of it is useful and valid. But information from companies comes mixed with hyperbole, bias, and misinformation, and there is often no way to tell which is which". (Page 250).

54. Counsel for the Rath Respondents suggested, somewhat half-heartedly, that Dr Venter and Professor Rollins are also litigants in this matter. That is plainly not the case. They are members of their professional association, which has 16 000 members. The professional association does not exist to promote its own good: its main purpose is *"to empower the medical profession in the Republic of South Africa to bring health to the nation"* (page 739). If members of the South African Medical Association are disqualified from giving expert evidence as to the nature and quality of various medical interventions, because that is related to the goal of the South African Medical Association of which they are members, then it would be impossible to find expert witnesses in cases in South Africa involving those issues in which SAMA is interested. Professionals are expected to be members of their professional associations. That cannot disqualify them from being witnesses with regard to matters in which their professional association, which seeks to act in the public interests, has an interest.

55. It is noteworthy that the Rath Respondents have not made any attempt to criticise in any way the quality or reliability of the evidence given by Dr Venter and Professor Rollins, except for Dr Rath's hyperbolic attacks on anyone who is a member of the medical profession.
56. Counsel for the Rath Respondents objects to the fact that the evidence of Professor Rollins was adduced in reply, and asserts that on that basis his evidence cannot be relied upon. This cannot be correct. In their answering affidavits, the Rath Respondents produced witnesses who claimed that they were able to give expert evidence, and who made certain claims with regard to medicines. The Applicants were entitled to answer that evidence by producing an expert witness who assessed the reliability of the claims made by the witnesses for the Respondents. That is how motion proceedings work. Again, the Applicants cannot be expected to produce witnesses in the founding papers who will anticipate who the witnesses will be for the Respondents, and what they will say, and then answer it in anticipation.

THE CLINICAL TRIALS

57. There is direct evidence of the clinical trials in the affidavits of the Khayelitsha Respondents. However, the clearest evidence is contained in what the Respondents themselves say they have done, and repeatedly say they have done. The objection of their counsel to the admissibility of this evidence is difficult to understand:

- 57.1 The Applicants produced evidence of what Dr Rath and his co-Respondents repeatedly said they had done.
- 57.2 Dr Rath and his co-Respondents did not deny having said that they had done these things.
- 57.3 Dr Rath and his co-Respondents did not say that what they had claimed in their advertisements was not true, and that in fact they had not done what they claimed in those advertisements.
58. Under those circumstances, it has been proved that they carried out those activities, on their own version.
59. Counsel for the Rath Respondents understandably did not attempt to explain on what basis it could be denied, if that evidence was admissible, that it constituted proof that the Rath Respondents carried out clinical trials.
60. It is common cause that the clinical trials were not approved by the MCC, and that it is unlawful to carry out clinical trials which have not been approved by the MCC.

THE REQUIREMENTS FOR A FINAL INTERDICT

61. We submit that the requirements for a final interdict are clearly met.
62. The facts show a clear right if unlawful activities are being carried on. In this instance the issue is really locus standi). It has been repeatedly accepted in litigation in our Courts, up to the level of the Constitutional Court, that the Treatment Action Campaign is entitled to litigate with regard to treatment for HIV/AIDS in its own interests. This is so because:
- 62.1 where a person encourages lay members of the public not to take the medicine which has been approved by the Medicines Control Council, but instead to take vitamins which have not been approved for this purpose, that constitutes a barrier or obstacle to access to effective treatment (clause 4.4 of the TAC Constitution, page 79); and
- 62.2 preventing the distribution of unregistered medicines, and the dissemination of false information, is necessary for the purpose of educating, promoting, and developing and understanding and commitment within all communities of developments in HIV/AIDS treatment (paragraph 4.5, page 80).
63. The TAC therefore has *locus standi* in its own right. It also acts in the public interest and on behalf of persons who cannot act in their own name

- for reasons of ignorance or lack of funds. By the nature of things, these people cannot be identified, and it is not necessary to have a “*mandate*” to represent their interests: if they were able to give such a mandate, they could be represented directly.
64. The TAC can act in the public interest because, in the words of the Constitutional Court in Ferreira v Levin, there is no other reasonable and effective manner in which this challenge can be brought before a Court.
65. The Second Applicant (SAMA) plainly has a special interest in protecting the health of the members of the public. The well-known Biko Doctors’ case – Veriava v President, SA Medical and Dental Council 1985 (2) SA 293 (T) – demonstrates the *locus standi* of individual members of the medical profession to ensure that the public is properly protected with regard to health matters. That must be all the more so where the applicant is the professional organisation of medical practitioners, representing 16 000 practitioners.
66. There is an injury actually committed or reasonably apprehended: the Rath Respondents are acting unlawfully. That is by itself an injury. They are disseminating false information, selling unregistered medicines, conducting unauthorised clinical trials and are unlawfully distributing scheduled substances. That is an injury.

67. It is not necessary to show an injury to particular individuals. However, even that has been shown. The evidence of the Khayelitsha deponents, and the evidence of Dr Saranchuk, both show that the health of people in Khayelitsha has been damaged by these unlawful activities.
68. There is no other effective remedy. Counsel for the Rath Respondents submitted that there was no evidence that the First Applicant had attempted to engage the police. This is wrong for two reasons:
- 68.1 First, it is wrong as a matter of fact. Mr Geffen states (paragraphs 185 – 189, pages 71 – 72) that the TAC lodged a complaint with the Health Professions Council (HPCSA) in March 2005 regarding the practice of Dr Rath without a licence. The HPCSA subsequently laid a complaint against Dr Rath, primarily on the basis on the evidence the TAC had provided, with the Khayelitsha Site B police. Mr Geffen and Mr Majola of the TAC provided extensive assistance to the police, including providing them with affidavits. On 6 June 2005 the TAC met with the police and a senior prosecutor at the Khayelitsha Magistrate’s Court. At this meeting they were asked to assist the police in setting up a “*sting*” operation against Dr Rath. They said that they would be willing to assist in this regard. Despite efforts by Mr Majola, nothing further has happened in this regard. None of this evidence has been disputed. It shows that other efforts have been made.

- 68.2 In any event, the evidence shows that this will not be an effective remedy. Mr Geffen has described how the efforts of the TAC came to nothing. The evidence of Mr Bell, which is also not disputed, is to the same effect. He states (page 728) that he followed the matter up with the Khayelitsha police, and no-one in charge could find the docket.
69. There is no other effective remedy available to the Applicants.

THE CITATION OF THE GOVERNMENT

70. Counsel for the Government Respondents accepts that it would be permissible to sue the Government *“as represented by the President”*. This must be so, given the large number of cases in which the Government is cited as either plaintiff or defendant. This amounts to a concession that section 2 of the State Liability Act is permissive, and not mandatory. The Act states that in proceedings against Government, the Minister of the Department *“may”* be cited as nominal defendant or respondent. The President is of course not a Minister or the Head of a Department. The acceptance that it is permissible to sue the Government represented by the President is an acknowledgement that it is not necessary to sue a particular Minister. That is permitted by the State Liability Act, but it is not compulsory.

71. Counsel for the Government Respondents repeatedly refer, in their heads of argument, to the Minister as the Eighth Respondent. That, however, is not the case. The papers are quite clear in their heading and in paragraph 17 (page 13) states that the Eighth Respondent is the Government of the Republic of South Africa.
72. We submit that that puts an end to this technical objection.
73. In any event, Counsel for the Government Respondents accepted in oral argument that the Minister of Health is properly before the Court. She is, according to the judgment of Kriegler AJA in the Raats-Rontgen case, the person whose Department is “*to provide the requisite administrative, policing and enforcement agencies*” under the Medicines Act. (At 263G: bundle page 10).
74. The Applicants would be perfectly happy to accept an order that the Minister of Health (who, it is common cause, is properly before the Court), is declared to be under a duty to take reasonable measures, is declared to have failed to take those measures, and is ordered to take them and report.
75. Counsel for the Government Respondents asked, in oral argument “*How is the Minister supposed to prevent distribution of medicines contrary to the Act?*” With due respect, that is quite a remarkable question. The answer is quite plain: she must cause proper investigations to be

undertaken; if the investigations reveal an offence, she must ensure that her officials draw this to the attention of the offenders, and attempt to persuade them to stop committing the offence; she must consider whether the matter should be made the subject of criminal proceedings; if she does so consider, she should enlist the support of the police and prosecuting authorities to play their role; and she should then give them whatever assistance they require. All of that is within her functions and indeed, her duties, as stated by Kriegler JA, as she has primary responsibility under the Act for “*policing and enforcement*” of its provisions.

76. It must be said, however, that the attempt to rely on the fact that the police and prosecuting services also have duties with regard to law enforcement is entirely artificial. If the Minister were to say: “*I accept that I have primary responsibility under the Act. I have carried out my duties, by doing the following I have tried to enlist the support of the police and the prosecutors in putting an end to these activities, but they have not done what they are supposed to do. Under the circumstances, I can’t be blamed for the failure of the Government to take effective action*”, then there might be some basis for saying the Minister of Safety and Security and the Minister for Justice and Constitutional Development should also be brought before the Court to explain what their Departments have done. That, however, is not her case. Her Department bears primary responsibility, as held by the Appellate Division. It has patently failed to take reasonable measures to investigate these serious allegations. It

follows that the Department for which she is responsible has failed to carry out its duty, and she is responsible for that as a matter of law. Her responsibility is of course as representative of the Government, which is the Eighth Respondent.

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