IN THE IDGHCOURT OF SOUTH AFRICA

(TRANSVAAL PROVINCIAL DIVISION)

In the matter between

Case number 24595/06

Date: 3/7/2006

NOT REPORTABLE

THE UNIVERSITY OF KWAZULU-NATAL — Applicant

and

THE MEDICINES CONTROL COUNCIL — Respondent

JUDGMENT

HARTZENBERG J

[1] This is an application for leave to appeal against an order, in terms of Rule 49(11) of the Rules of Court, granted by Mabesele AJ on 2 April 2007. The learned judge had to decide two matters, an application for leave to appeal against a judgment of Makhafola AJ and an application in terms of Rule 49(11) which sought the enforcement of the order, pending an appeal against it. He upheld both applications. The order of Makhafola AJ was a mandamus, directing the respondent to give effect to a decision of

an Appeal Committee, constituted in terms of the Medicines and Related Substances Act, No.101 of 1965 (*"the Act "*), upholding the appeal of the applicant against the refusal of the respondent to approve the clinical trial, described as Protocol HPTN 046 and directing the respondent to approve the aforesaid clinical trial.

[2] The clinical trial focuses on research into the prevention of mother to child transmission of the Human Immunodeficiency Virus (HIV) through breastfeeding. Approximately 40% of mothers who arrive at antenatal clinics in Kwazulu-Natal are HIV positive. One third off all mother-to-child transmissions occurs through breastfeeding. At the clinics mothers are advised about the advantages and disadvantages of breastfeeding as opposed to formula feeding. But for the risk of HIV transmission there are advantages to breastfeeding in that in rural areas it may be more hygienic than formula feeding because of poor facilities and breastfed babies are also more resistant to certain illnesses than formula fed babies. In Kwazulu-Natal 70% of all HIV infected mothers choose to breastfeed to avoid the embarrassment and social disgrace that goes with being HIV positive, even though free formula is provided. The reality is further that in the foreseeable future they will continue to breastfeed. It is evident that if a method can be devised to prevent or reduce the transmission of HIV from mother to child during the period of breast feeding, that many early deaths and many hardships can be avoided.

[3] The clinical trial, Protocol HPTN 046, seeks to research the effect of Nevirapine as a prophylaxis to reduce mother to child transmission in breastfeeding mothers. Nevirapine has been registered by the respondent and has been found to be

safe. There can therefore not be any objection against the clinical trial based on the use of Nevirapine. I understand that the clinical trial will involve monitoring the results obtained in respect of 360 HIV positive mothers who chose to breastfeed, of whom in the case of 180, Nevirapine is provided, and in the case of the other 180, placebos are provided[1]. The same diet will be made available to all the women and children. If there are a significant lesser number of transmissions in the case of the babies where Nevirapine was administered than in the case where it was not administered, it will prove that the risk of transmission through breastfeeding can be reduced by the use of Nevirapine, during the period of breastfeeding. The result of the clinical trial will at worst be that no transmission has been avoided. If on the other hand Nevirapine is effective for this purpose, it may cause the avoidance of transmission in a number of cases of mothers the infants of whom received Nevirapine. In the case of the other 180 mothers and babies their position will be the same than what it would have been had the clinical trial not been done, except for the better diet from which they benefited.

[4] A multidisciplinary international team developed the clinical trial. It was some time ago because the National Institute of Health, one of the three largest funding institutes in the world, awarded a sum of over R47 million to the project. The monies

[1] A relevant consideration is articulated as follo ws in the *Guidelines for Good Practice in the Conduct of Clinical Trials in South Africa:*

> "Ethical guidelines that apply to controlled therapeutic trials are generally sufficient to protect the rights of HIV-infected persons. '. A special case involves the use of placebo after an intervention has been shown to be effective. The general principle is that the use of placebo in these circumstances is unethical. However, with increasing disparities in health care between wealthy and poor countries, therapy that has been shown to be effective is often unaffordable in resource-poor settings. This is particularly true of therapeutic advances in HIV infection, which is a far bigger health care problem in poor countries in sub-Saharan Africa than it is in the industrialized countries. It may be justifiable to use placebo in communities that do not have access to interventions that are the standard care in resource-rich settings.

were to be paid out, in five installments, over a five year period from 1 July 2003 until 30 June 2008.

[5] The applicant, through the Nelson R Mandela School of Medicine, applied to the respondent, on 25 November 2003, to approve the clinical trial in terms of the provisions of the Act. Despite prompt reaction from the applicant, on each occasion that the respondent had lost some of the documents or required more information, it was only more than a year later, on 9 December 2004, that the applicant was informed that the respondent had refused the application.

[6] Thereafter the applicant lodged an appeal to an Appeal Committee in terms of section 24(3) of the Act. The appeal was lodged on 30 December 2004. Although an Appeal Committee has to be constituted within 30 days, the committee was only constituted later and the appeal was ultimately only heard on 16 and **17** August 2005. The committee consisted of members with skills relevant to the case concerned. The hearing took the form of written and oral submissions and both the applicant and the respondent led the evidence of witnesses who were subjected to cross-examination. The parties were to submit further written argument by 31 August 2005. It was agreed that the committee was to deliver its decision by 30 September 2005. Eventually the Appeal Committee only delivered its aforesaid decision on 28 February 2006. The decision was the following:

(a) The applicant's appeal against the respondent is upheld; and

(b) The Respondent is ordered to approve the clinical trial applied for by the applica nt.

[7] After some correspondence the respondent advised the applicant on 11 April 2006 that it had resolved to take the decision of the Appeal Committee on review to the high court. The applicant tried to resolve the issue but the respondent's only proposed solution to the issue was that the applicant was not to oppose an application for the review of the decision of the Appeal Committee, by the respondent. On 29 June 2006 the applicant as a last resort resolved to apply to the high court for a mandamus that will compel the respondent to give effect to the decision of the Appeal Committee. The applicant's notice of motion is dated 26 July 2006.

[8] In its answering affidavit the respondent states that it is taking the decision of the Appeal Committee on review and it attaches its founding affidavit in that matter to the answering affidavit. The review application was lodged after the application for a mandamus. The applicant contends that a review is bad in law as the respondent has no *locus standi* to take the decision on review and that it has no case on the merits as it only sought a declaration to the effect that the chairman of the Appeal Committee exceeded his powers. It is the applicant's case that the respondent's review application is premised upon the supposition that the Appeal Committee does not have

the power to substitute its decision for the decision of the respondent. It contends that section 24(3) of the Act[2] is clear and unambiguous and bestows the powers on the Appeal Committee that it exercised and that the respondent has thus far failed to even suggest a plausible interpretation of the section upon which it can rely for its contention. Moreover the applicant contends that the order of Mabesele AJ is not appealable as it is an interlocutory order and that the application ought not to be entertained as the respondent is seriously disregarding an order of court and the Rule of Law

[9] The respondent contends that the effect of upholding the rule 49(11) application amounts to a final order. If the clinical trial is to be registered now and the trial commences, the appeal, for which leave has now been granted and the review application have both become academic as the continuation of the tria1will be irreversible. Even if the appeal or the review or both succeed, the clinical trial will be in progress and it will not be possible to deregister the clinical trial. It is argued that the Appeal Committee did not approve the clinical trial but ordered the applicant to do so. The argument seems to be that the Appeal Committee was not entitled to do so. It is argued that when a court determines whether it is just and equitable to grant interim execution of an order, the court should have regard to the potentiality of irreparable harm to both parties and that it is not to grant interim execution to a successful litigant if it would cause irreparable prejudice to the opponent if eventually an appeal succeeds. By the same token it is not to refuse interim execution if the applicant will be irreparably

[2] It provides as follows:

> "*The appeal committee may, after hearing the appeal*
> *(a)confirm, set aside or vary the relevant decision of the council; and*
> *(b) direct the council to execute the decision of the appeal committee.*

prejudiced if eventually the appeal is dismissed[3]. The argument is then that there were two conflicting rights i.e. the right to life by children who stand to be infected with HIV as a result of the clinical trial and the right of the applicant to receive R47 million in order to implement the clinical trial, and that the learned judge failed to weigh those conflicting considerations properly up against one another. The respondent also at a late stage in the proceedings resorted to an argument that the clinical trial is designed in such a way that the lives and well being of black women and children are sacrificed for the benefit of more affluent communities.

[10] The very first question to be asked is whether there is any merit in the respondent's argument that the Appeal Committee did not have the authority to direct the respondent to register the clinical trial. I am at a loss to understand the respondent's argument. The Act specifically provides for an appeal against a decision of the respondent. It emphatically empowers the appeal tribunal, the Appeal Committee, to "reverse" the decision of the respondent and to "direct" it to implement the decision of the Appeal Committee. That is exactly what the Appeal Committee has done. There is no merit in the respondent's argument that the Appeal Committee did not have the authority to make the order which it made or that it is not bound by it. In my view it is extremely unlikely that a court of appeal will find that the Appeal Committee was not entitled to come to the decision to which it had come.

3 *South Cape Corporation (Pty) Ltd* v *Engineering Managing Services (Pty) Ltd,* 1977 (3) SA 534 (A) at 551/2

[11] It follows then that for the review to succeed the court hearing the review must find that the Appeal Committee failed to take into account that there are ethical objections against clinical trials where placebos are administered. The true position is that the Appeal Committee was very alive to that question. Lengthy submissions were made on this very point and there is not the slightest possibility that this aspect was overlooked by the Appeal Committee. For example in paragraphs 32.5 and 32.6 of its decision the following statements were made:

> "*From a scientific viewpoint this study proposed to compare an intervention (breast-feeding plus nevirapine prophylaxis) with standard practice (breast feeding with no intervention (placebo)). By no means is the standard practice ideal, but it represents a practice occurring daily at under-privileged and under resourced environments.*"
>
> "*The proposal has the potential of providing information which could strengthen the prevention of mother-to-child transmission and would save the lives of many babies in future.*
> "

It would indeed be a very difficult task for the respondent to persuade the court hearing the review application that the Appeal Committee failed to apply its mind to the issues, with which it had to deal. In this regard it is important not to overlook the fact that the clinical trial does not place any mother or child in a position worse than what they would have been, had the clinical trial not been done. The emotional cry of the respondent that the clinical trial will lead to the infection of innocent babies with HIV is simply not true.

The argument that the experiment is an exploitation of an under-privileged black community for the benefit of more affluent communities is equally unsound. The people

[13] I do not think that the effect of the order is final. If the appeal or review is successful after having been prosecuted diligently in terms of the various rules of court, there may still be a major portion of the five year period over which the clinical trial is to be done which is unexpired. The remainder of the experiment can then be cancelled. But even if I am wrong in that regard Mabesele AJ had to weigh up the prejudice which the applicant will suffer if the order is not implemented against the prejudice which the respondent will suffer if the order is implemented. In the process he was entertained on an untenable argument about the powers of the Appeal Committee and on an equally untenable argument as to whether the Appeal Committee exercised its discretion judicially. Moreover it was evident that the respondent was obstructive in an attempt to have the application disappear. It is more than three and a half years since the original application was lodged. The delaying tactics of the respondent is in my view a factor to be taken into account when a court has to decide whether it is just and equitable to order implementation of its order or not. If the respondent acted reasonably in appealing with the leave of Mabesele AJ it is now of the result that, as is likely, in favour of the applicant the clinical trial could have been well on its way. Assuming however that it is appealable, the prospects of success on appeal with the review application are so slim that the application for leave to appeal should also be dismissed with costs.

The application for leave to appeal is dismissed with costs.

W J HARTZENBERG

involved with the application work daily in that community and experience the hardship caused by the transmission of HIV from mother to child. They can, whilst doing that work, contribute something by possibly devising a method of reducing the transmission. It is not as if they have scanned the world map and arbitrarily decided to pick Kwazulu Natal as the place where they wanted to conduct a life threatening experiment on the applicant.

[12] A very perturbing feature of this application is the respondent's conduct which cannot but give the impression that the respondent deliberately delayed matters in an attempt to have the application disappear. It is more than three and a half years since the original application was lodged. The delaying tactics of the respondent is in my view a factor to be taken into account when a court has to decide whether it is just and equitable to order implementation of its order or not. If the respondent acted reasonably in appealing with the leave of Mabesele AJ it is now of the result that, as is likely, in favour of the applicant the clinical trial could have been well on its way. Assuming however that it is appealable, the prospects of success on appeal with the review application are so slim that the application for leave to appeal should also be dismissed with costs.

The application for leave to appeal is dismissed with costs.

W J HARTZENBERG