iAfrica Transcriptions (Pty) Limited/jl

IN THE HIGH COURT OF SOUTH AFRICA
(NORTH GAUTENG HIGH COURT, PRETORIA)

CASE NO: 57976/11

DATE: 2011-11-15

DELETE WHICHEVER IS NOT APPLICABLE
(1) REPORTABLE YES/NO
(2) OF INTEREST TO OTHER JUDGES YES/NO
(3) REVISED

DATE 27/2/12 SIGNATURE

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In the matter between

MEDICINES CONTROL COUNCIL	1st Applicant
REGISTRAR OF MEDICINES	2nd Applicant
MINISTER OF HEALTH	3rd Applicant
DIRECTOR-GENERAL DEPARTMENT OF HEALTH	4th Applicant

and

ADCOCK INGRAM LTD	1st Respondent
ADCOCK INGRAM HEALTHCARE (PTY) LTD	2nd Respondent

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In re:

ADCOCK INGRAM LTD	1st Applicant
ADCOCK INGRAM HEATHCARE (PTY) LTD	2nd Applicant

And

APPEAL COMMITTEE	1st Respondent
THE MINISTER OF HEALTH	2nd Respondent

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JUDGMENT

BERTELSMANN J: The applicant approaches the court to have a settlement agreement that was made an order of court by my brother

Hiemstra AJ, set aside on the grounds that:

a) It was entered into by its legal representatives, without authority;

b) The settlement agreement exceeded the applicant's statutory powers

c) The settlement agreement was prejudicial to the applicant; and

d) That the settlement agreement was not in the public interest.

At the centre of the dispute between the parties is the decision which the first applicant, the Medicines Control Council, (MCC) took during April 2011 that medicines containing dextropropoxyphene (DPP)
10 should be withdrawn from the market and that their registration should be cancelled.

The first respondent, Adcock Ingram Ltd, markets three separate medicines, namely Synap Forte, Lentogesic and doxyfene which contain DPP. These medicines are very effective pain relieving medications. However, according to the experts relied upon by the first applicant and the evidence that was placed before the court, medicines containing dextropropoxyphene create risks for patients because of their cardiotoxicity. These significant risks may cause both inadvertent death and serious renal problems, particularly in elder patients who use these
20 medicines for pain relief.

The MCC eventually decided to withdraw the registration of any medicine containing dextropropoxyphene and issued a letter to health care practitioners in which they were advised of this fact.

The deregistration was preceded by an announcement that health care practitioners should wean their patients off these medicines over a

period of 3 months, as some patients may have become dependent upon, or habituated, as it was put by Mr Marcus, to these medicines.

Once the 1st applicant deregistered the above medicines the respondents, Adcock Ingram Ltd and Adcock Health Care (Pty) Ltd, launched an urgent application for the suspension or withdrawal of the letter to the health care practitioners. They sought an order which entitled them to sell their medicines pending the administrative appeal against the decision to withdraw these medicines from the market, which appeal had already been launched.

10 In spite of the fact that the State Attorney, acting for the applicant, had not been authorised there to by either the Medicines Control Council or the Registrar of Medicines or the Minister of Health or the Director General of Health, the legal team instructed by the State Attorney on behalf of the applicants entered into a settlement agreement with the respondents, that not only allowed Adcock Ingram Ltd to continue to sell their medicines, but suspended the operation of the 1st applicant's decision and allowed Adcock Ingram access to the otherwise confidential minutes of the first applicant's deliberations.

The MCC approached this court as matter of urgency within a matter

20 of 48 hours after having become aware of the fact that this settlement had been entered into. Applicants seek revocation of the order that made the settlement an order of court on the grounds that no instruction to enter into such settlement had been given to the State Attorney or the counsel representing the parties.

First applicant agues further that it was not statutorily entitled or

empowered to enter into such a settlement agreement.

In this connection, it should be pointed out that the administrative appeal which is provided for in the Medicines Control Act, is exactly that. It is no appeal in terms of the common law of a judicial nature, which would suspend an order against which it has been launched.

A decision by the Medicines Control Council remains effective until it has been set aside, either by the appeal process or by order of a competent court or is effectively overruled by a subsequent successful new application for the registration of a similar or the same medicine.

10 There is no statutory power conferred upon the Medicines Control Council to suspend a decision *mero motu* or otherwise once it has decided to deregister a medicine, unless of course thereafter, the council considers a new registration on new evidence.

But in the interim, while the medicine has been deregistered, there is no room for the argument that such a decision could be suspended pending appeal or further proceedings.

On this basis alone, the settlement agreement was clearly ultra vires and lacked legality.

Adcock Ingram Ltd, the respondents, rely on estoppel and on

20 ostensible authority of the applicant's legal representatives. Respondents refer to *MEC for Economic Affairs, Environment and Tourism, Eastern Cape v Kruizenga & another 2010 (4) SA 678 (SCA)* in support of their argument.

There is an essential difference between the facts that underlie the Supreme Court of Appeal decision referred to and the present facts.

In this instance, as I have already underlined, the 1st applicant does

not have the statutory authority to enter into a settlement agreement of the nature that is under discussion here.

Quite apart from that, there is little doubt about the fact that the fall-out, both administratively and otherwise, would be considerable for the applicants, if the settlement agreement were to stand.

The whole ratio of the decision to deregister the medicines has always been the public interest.

There may be a debate about whether the medicines ought to have been withdrawn at this stage. They have been around for 38 years. There
10 may be a debate about the measure of toxicity that exists in the various medicines and there may be a debate about the statistics the parties rely upon for their point of view.

There may be disputes about whether there have been many or few proven deaths that could be attributed directly to the use of any of the medicines.

It is not for this court at this stage to decide any of these issues. What is clear and undisputed is that the 1st applicant has at all times acted in the public interest.

A decision which first applicant, in its specialist professional capacity,
20 regards as essential, as necessary and in the public interest, cannot thereafter be revoked. A most unfortunate error on the part of 1st applicant's legal representatives, which should never have occurred, has led to a purported suspension of a decision the statute does not allow to be suspended

Under the circumstances there is no room for the argument that the

applicants are estopped from seeking to have the settlement agreement set aside.

Prayers 2, 3 4 and 5 of the notice of motion, rescinding the order and setting aside the settlement agreement, granting leave to the applicants to oppose the main application and granting leave to file an answering affidavit must be granted.

It follows that the counter application must be dismissed.

The question of costs must be decided. Normally, in a matter of this nature, costs would follow the result.

10 And normally in a matter of this nature, that would include cost of two counsel, because obviously the matter was of very significant importance to all the parties concerned and the employment of two counsel was fully justified.

The court has been greatly assisted by the contributions of both sets of counsel who have appeared on behalf of the protagonists.

However, the court must in some manner express its dismay at the fact that the State Attorney and those instructed by him allowed this settlement agreement to be concluded, thereby causing the chain of unfortunate events that ended in this court today.

20 This is not the place to expand upon this issue, other than to record that it is a most unfortunate occurrence that one hopes will never occur again.

After all, the State Attorney is the custodian of public funds and is responsible for the representation of all our government institutions and organs of state.

And they would be the first to agree that in this case, the professional standard they aspire to has not been met.

ORDER

Under the circumstances, the fairest approach must be that no order as to costs is made.

Consequently, prayers 2, 3, 4 and 5 of the notice of motion are granted and the counter application is dismissed.

COURT ADJOURNS

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10 ON BEHALF OF THE APPELLANT: ADV G MARCUS (Sc)

ON BEHALF OF THE RESPONDENT: ADV B BREDENKAMP (Sc)