IN THE HIGH COURT OF SOUTH AFRICA

NORTH GAUTENG HIGH COURT, PRETORIA

DELETE WHICHEVER IS NOT APPLICABLE
(1) REPORTABLE: ~~YES~~/NO.
(2) OF INTEREST TO OTHER JUDGES: ~~YES~~/NO.
(3) REVISED.
11/11/13
DATE SIGNATURE

11/11/13

CASE NUMBER: 14858/2013

In the matter between:

MEDICINES CONTROL COUNCIL **APPLICANT**

and

THE MINISTER OF HEALTH **1ST RESPONDENT**

NEW CLICKS SA (PTY) LTD **2ND RESPONDENT**

NATAL WHOLESALE CHEMISTS (PTY) LTD T/A

ALPHA PHARM PHARMACEUTICAL WHOLESALERS **3RD RESPONDENT**

JUDGMENT

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1. The third respondent applied in 2004 to the applicant for a licence to export medicines to, in particular, neighbouring states. The applicant is the Medicines Control Council, a statutory body and juristic person created by

section 2 of the Medicines and Related Substances Act 101 of 1965 ("the Act"), with principal place of business at Civitas Building, 42 Thabo Sehume Street, Pretoria.

2. The second respondent launched a similar application in 2011.
3. The first respondent cited in these proceedings is the Minister of Health of the same address as the applicant. He is the political head of the Department of Health. One of his functions is to appoint an appeal committee whenever an unsuccessful applicant for a licence which had to be applied for in terms of section 22C of the Act wishes to appeal against the refusal of the applicant to grant the license sought. This function is exercised in terms of section 24 of the Act. The parties are agreed that the Minister was incorrectly cited and has no role to play in these proceedings. The bodies that should have been joined by the applicant were the two *ad hoc* Appeal Committees, which informed the court through their respective chairpersons that they would abide by the court's decision.
4. The second respondent is New Clicks SA (Pty) Ltd, a company registered in accordance with the company laws of the Republic of South Africa. Its division that applied for the export licence is United Pharmaceutical Distributors which does business at 14 Tamar Avenue, Lea Glen, Roodepoort, Gauteng.
5. The third respondent is Natal Wholesale Chemists (Pty) Ltd a company registered in accordance with the company laws of South Africa, trading as Alpha Pharm Pharmaceutical Wholesalers, with principal place of business at 18 Voortrekker Street, Newcastle.
6. Both second and third respondents, as stated above, applied for licences to export medicines and medical devices. The applications were heard on

separate dates by the applicant, but both were refused on the same ground, namely that the applicant was not, in its view, empowered to grant an export (or import) licence to any person or entity other than a manufacturer. The applicant relies on this approach upon its interpretation of section 22C(1)(b) of the Act. The relevant section reads as follows:

> *' Subject to the provisions of this section*
>
> *a).....*
>
> *b) the council may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medicine or medical device a licence to manufacture, import or export, act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine.'*

7. This section was amended in 2002.

8. The amendment introduced the words '*import or export*' into the section. The second and third respondents relied upon the introduction of these terms into the section when they applied for a licence to export medicines.

9. According to the applicant, the wording of the section, interpreted according to its syntax, clearly restricts the power to award an export licence to a manufacturer. Its principal plank upon which this submission rests is the meaning the applicant ascribes to the words ' ... as the case may be ..'. If I understand the argument correctly, the applicant contends that this phrase restricts the power to grant an import or export licence to the manufacturer as the category mentioned first in the subsection, only, because the phrase ' *..manufacture, import or export..*' is the first group of verbs that must be aligned to the first-mentioned category of traders in medicines.

10. The licence to act as wholesaler must by the same token be restricted to wholesalers only, and the licence to distribute must be restricted to licensed distributors, so goes the argument.

11. The applicant finds support for its approach in the wording of section 22H, which determines that:

> ***'22H Purchase and sale of medicines by wholesalers***
>
> *(1) (a) No wholesaler shall purchase medicines from any source other than from the original manufacturer or from the primary importer of the finished product.*
>
> *(b) A wholesaler shall sell medicines only into the retail sector.*
>
> *(2) Subsection (1) shall not be construed as preventing the return of medicines for credit purposes only, to the manufacturer or wholesaler from which that medicine was initially obtained.*
>
> *(3) Any wholesaler may in the prescribed manner and on the prescribed conditions be exempted by the Director-General from the provisions of subsection (1).'*

12. Applicant also points to the definition of '*sell*' in clause 1of the Act and argues that the absence of the word '*export*' from the otherwise very extensive definition is congruent with the interpretation that export activities cannot be conducted by traders but only by manufacturers:

> *''sell' means sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise; and 'sale' and 'sold' have corresponding meanings..'*

12. The interpretation contended for by the applicant is clearly in conflict with the fundamental tenet and first principle of the interpretation of statutes that words, phrases and sentences should be given their ordinary meaning. The words '*...as the case may be ..*' clearly have the opposite meaning of that

proposed by the applicant. They mean no more and no less than that the three categories of traders, namely manufacturers, wholesalers and distributors, as the case may be, may be licensed to export medicines in addition to the activity they are already authorised to perform. Applicant's interpretation presents a tortured reinterpretation of the natural semantic content of the words and grammar employed in the section, which approach, with all due respect, is contrived and nonsensical.

13. The applicant's approach leads to an absurd situation: Imported medicines may only be obtained and received by a manufacturer; must be sold only to a wholesaler who may only sell to a distributor who is the only entity entitled to supply the public – a costly, time consuming exercise that will be beset by red tape and delay, by increased frustration and dissatisfaction on the part of the consumer and by increased temptation to bypass a process that does anything but advance business efficacy.

14. Most importantly, however, the applicant's approach runs counter to the judgment in *Minister of Health & Another NO v New Clicks (Pty) Ltd South Africa & Others (Treatment Action Campaign & Another as* amici curiae) 2008 (1) BCLR 1 (CC) (2006 (2) SA 311 (CC)). The matter concerned the validity of regulations relating to the pricing of medicines, but in the process of analysing the Act and its Regulations Chaskalson, CJ, who delivered the main judgment, had to comment upon the Act's and Regulations' provisions dealing with import and export of medicines and the entities entitled to do so. He said the following:

'[218] The Medicines Act requires persons engaged in the making and distribution of

medicines and scheduled substances to be licensed to do so. This is dealt with in section 22C of the Medicines Act and in the General Regulations. In terms of sections 22C(1)(b) and 22C(6) manufacturers, distributors or wholesalers licensed to do so may import medicines With the exception of section 15C, which deals with parallel importing of patented medicines, no other section of the Medicines Act authorises anyone other than a manufacturer, wholesaler or distributor to import medicines or scheduled substances. It is not clear from section 15C whether persons engaged in parallel importing in terms of that section also require to be licensed under section 22C, but that need not be decided in this case. ...

[238] *The regulations define an importer as*

"a person importing medicines for the purpose of sale in the Republic from a manufacturer or other person outside of the Republic and includes a parallel importer as defined in the Act".

There is no definition of "parallel importer" in the Medicines Act. Presumably the reference was intended to be to a person importing medicine in terms of section 15C of the Medicines Act, and this is how the words are defined in the General Regulations.

[239] *When they refer to an importer in the "supply chain" the regulations may be understood as referring to a person other than a manufacturer, distributor or wholesaler. This is also what may be inferred from the way the definitions of logistics fee, logistical services, single exit price, retailer, and user are formulated in the regulations, and also from regulations 6, 14, 21, 22(1), and 24.*

[240] *The definition of importer in the pricing regulations also contemplates that importers will be engaged in selling medicines. Regulation 24(4) says as much. It provides that:*

"Manufacturers and importers must, with effect from the date one month after the date of commencement of these regulations, sell medicines and scheduled substances only in accordance with the provisions of these regulations."

[241] *In this context the regulations must be construed as referring to lawful importers To act lawfully, importers must be licensed in terms of the Medicines Act. And the Medicines Act only makes provision for such licences to be issued to manufacturers, distributors and wholesalers.*

[242] *The regulations define "distributor" as meaning:*

"a person, other than a manufacturer, wholesaler or retailer, who supplies a medicine or Scheduled Substance to a retailer or wholesaler".

The definition refers to "supply" and not to "sell". This is consistent with the Medicines Act which does not permit distributors to sell medicines or Scheduled substances for

their own account. They may, however, import the medicine on behalf of the manufacturer, and if licensed to do so, they become importers as well.

[243] *"Wholesaler" is defined as meaning:*

"a dealer who purchases medicines or scheduled substances from a manufacturer and sells them to a retailer and includes a wholesale pharmacy".

This is also consistent with the Medicines Act which requires wholesalers to buy from manufacturers. If they do so they may in the process become "importers".

.....

[251] *I also do not agree that the Medicines Act draws a clear distinction between manufacturers, wholesalers and distributors on the one hand and importers on the other. It does draw a distinction between manufacturers, wholesalers and distributors, but it recognises that each may import medicine and Scheduled substances and, with the possible exception of importing in terms of section 15C, does not permit anyone else to import such products. It is possible that a particular manufacturer, wholesaler or distributor may not be licensed to import medicine, and to that extent there may be a distinction between those who are licensed to import and those who are not. But importers are not "a genus different from manufacturers"; manufacturers licensed to do so may import.*

15. Apart from the judgment by Chaskalson CJ, judgments were penned by Langa DCJ, Ngcobo J, Sachs J, Moseneke J, O'Reagan J, Yacoob J and Van der Westhuizen J. None of these dealt with the interpretation of section 22C(1)(b), or of the relevant Regulations, and none differed from the parts of the then Chief Justice's judgment quoted above. Mr Notshe SC on behalf of the applicant argued that these comments were *obiter* and unnecessary for the issue which the honourable Constitutional Court had to decide. This submission is incorrect. The structure of the Act and the various provisions introduced into it to ensure an affordable pricing regime for medicines that need to be supplied to the public was clearly of relevance when dealing with the Regulations determining prices. And even if the remarks could be said to

be *obiter* they are directly in point and eminently persuasive. They clearly demonstrate that the applicant's approach was and is untenable. There simply can be no doubt whatever that the reasoning of the judgment quoted above must apply with equal force to export licences as it does to import licences.

16. The applicant's reasoning was rejected by both the Appeals Committees constituted to deal with the second and third respondents' appeals launched after the applicant refused their applications on the grounds stated above. The Appeals Committee constituted to hear the third respondent's appeal delivered its judgment on the 7th June 2012. The appeal judgment relating to the second respondent's appeal was delivered on 21 November 2012.

17. The parties are *ad idem* that the Promotion of Administrative Justice Act 3 of 2000 ("PAJA") applies to these proceedings and that the applicant was therefore obliged to comply with section 7(1) thereof. It provides that judicial reviews must be instituted without delay and not longer than 180 days after the decision was communicated to the applicant concerned. The court may grant condonation of the failure to launch a review in time where the interests of justice so require. As part of the consideration of the interests of justice there must be a reasonable explanation of the delay.

18. The applicant failed to launch the review within 180 days in respect of the third respondent's appeal, but was in fact 90 days out of time when the present review was issued on the 7th March 2013. The review was in time as far as the second respondent's appeal is concerned, but still more than three months after the judgment on appeal was handed down. Both respondents repeatedly communicated through their attorneys with the applicant prior to

the launching of the review application, demanding compliance with the appeal judgments by the applicant's consideration of the applications for export licences. No such step was taken and second and third respondents had to endure further delay until the review was eventually launched. The failure to do so in time is explained by the applicant's deponent, dr Khomo, the applicant's deputy chairperson, in terms that could not be more laconic and superficial:

> *'The delay was caused by the fact that the applicant was seeking advice as to the course of action to be taken. On the one hand it wants to maintain its independence and carry out its functions without fear or favour. On the other hand it does not wish to easily institute legal proceedings. This Honourable Court has been approached as a last resort.'*

This is no explanation at all, particularly because the review is based upon the self-same grounds upon which the licences were refused and that were advanced on appeal. Given the sorry history of procrastination in respect of the third respondent's application, which will be dealt with more specifically below, this excuse demonstrates applicant's disregard of the respondents' rights and another failure to comply with its duty to deal with applications for licences speedily, transparently and efficiently. Had the matter not been of singular public importance and had this explanation to be considered on its own, no condonation could have been granted. Both respondents desired to deal with the matter, however, and condonation was granted as a result thereof in the light of the clear public interest involved in deciding the issues at hand.

19. It has been recorded above that the applicant had delayed its decision on the third respondent's application for an export licence for a full seven years before taking a (wrong) decision. There is no explanation, no justification and no apology for this extraordinary failure to perform its functions timeously in spite of repeated reminders by third respondent's legal representatives. The third respondent raised the extraordinary delay in taking a decision on its application in its answering affidavit. The second respondent complained in its answering affidavit about the failure to implement the findings of the Appeal Committee and the delays experienced in the proceedings preceding the hearing of its appeal. The applicant chose not to file a replying affidavit – without any explanation – with the result that the second and third respondents' complaints are uncontested. It should be remarked in passing that applicant's heads of argument were filed out of time and that applicant's legal representatives – the State Attorney – failed to paginate and index the papers to prepare them for argument. This function was undertaken by second respondent.

20. In the light of this history, third applicant seeks a punitive costs order which is clearly justified. The claim for attorney and client costs was not strongly contested in argument.

21. It remains to be added that both Appeals Committees awarded costs orders against the applicant. The parties are agreed that they had no power to do so and that that part of each finding on appeal must be set aside in so far as the second and third respondents have not already abandoned those orders.

The following orders are made:

1. The application for a review of the Appeals Committees' findings that applicant is obliged to consider the second and third respondents' applications for licences to export medicines is dismissed with costs;
2. Such costs are to be calculated on the basis that the employment of senior counsel was justified and, in respect of the third respondent, are to be calculated on the scale of attorney and client;
3. It is recorded that the applicant is obliged, in terms of the Appeals Committees' orders, to consider second and third respondents' applications referred to in 1. above within thirty days from date hereof;
4. The respective award of costs made by the Appeals Committees is set aside.

Signed at Pretoria on this 11th day of November 2013.

E BERTELSMANN

Judge of the High Court