Not reportable 19 March 2009

IN THE HIGH COURT OF SOUTH AFRICA

[NORTH GAUTENG HIGH COURT, PRETORIA]

CASE NO: 25382/2008

In the matter between:

TECMED AFRICA (PTY) LTD Applicant

and

MINISTER OF HEALTH First Respondent

CANCARE (PTY) LTD Second Respondent

AND

CASE NO: 30841/2008

In the matter between:

TECMED AFRICA (PTY) LTD Applicant

and

THE DIRECTOR GENERAL: NATIONAL HEALTH First Respondent

CANCARE (PTY) LTD Second Respondent

MINISTER OF HEALTH Third Respondent

JUDGMENT

Delivered……..

R D CLAASSEN J:

This judgment concerns two applications, numbers 25382/08 and 30841/08. Both are review applications to set aside certain decisions/actions by the Director General and the Minister respectively of the Department of Health. They were heard together because all were agreed that they are inexplicably linked. I shall refer to the Respondents variously as the "Minister", the "DG" and "Cancare". "*Respondents*" shall mean the DG and the Minister.

2.

In Case No. 25382 the following relief is sought against the Minister.

"*1. (Urgency – Not relevant)*

2. 2.1 That the decision of the First Respondent dated 23 May 2008 in respect of the appeal to her by the Applicant dated 5 May 2008 in terms of Section 6 of the Hazardous Substances Act 15 of 1973 (the Act) that:

(a) the appeal <u>is dismissed</u>;

(b) the <u>embargo continues</u> to apply until such time that Tecmed complies with the

requirements for a licence to import or manufacture the listed electro-medical products, be reviewed and set aside

2.2 That the appeal by the Applicant to the First Respondent dated 5 May 2008 in terms of Section 6 of the Act, be upheld.

3. Alternatively, to paragraph 2 supra:

3.1 Pending a final determination of the relief sought in paragraph 2 above, that:

3.1.1 The decision of the Director General purportedly taken in terms of Section 9A of the Act, to place an embargo on licences held by the Applicant; and

3.1.2 The dismissal by the First Respondent of the appeal against the decision referred to in paragraph 3.1.1 supra: are suspended.

4. Costs of suit to be paid by the First Respondent."

(My emphasis)

3.

In case number 30841 the following relief is sought:

"*1. (Urgency – not relevant)*

2. Exempting the Applicant from any obligation which it may have to exhaust any internal remedies which may exist or have existed as contemplated in Section 7(2) of the Promotion of Administrative Justice Act, 3 of 2000;

3. 3.1 That the decision by the First Respondent to refuse to issue to the Second Respondent a licence to sell, let, use, operate or apply a Group III Hazardous Substance in terms of the Second Respondent's application dated 15 March 2008, be reviewed and set aside.

3.2 Alternatively to paragraph 3.1 supra declaring that the grounds advanced by the First Respondent in refusing the Second Respondent a licence for use of the Varian Clinac 2000 CR situated at Durban Oncology in relation to the purported transgressions by the Applicant, as

foreshadowed in the affidavits filed of record, have no foundation in fact and/or in law.

3.3 *Directing the First Respondent to issue a licence to the Second Respondent, as contemplated in Section 41 of the Hazardous Substances Act, 15 of 1973 for use of the Varian Clinac 2000 CR situated at Durban Oncology.*

4. *Alternatively to paragraph 3 supra, pending a final determination of the relief sought in paragraph above, that the First Respondent is restrained from taking any steps whatsoever towards prohibiting the Second Respondent from utilising the Varian Clinac 2000 CR Linear Accelerator, situated at Durban Oncology.*

5. *Alternatively to 3 and 4 above, pending a final determination of the relief sought in paragraph 3.1 alternatively 3.2 above, that the First Respondent issue a licence to the Second Respondent as contemplated in Section 4(1) of the Hazardous Substances Act, 15 of 1973 for use of the Varian Clinac 2000 CR situated at Durban Oncology.*

6. *Costs of suit to be paid by the First Respondent.*"

(My emphasis)

4.

In both cases the Second Respondent "*Cancare"*, being a very interested party, supports the applications. I shall refer to the first case, No. 25382, as the "*embargo application*" and to the second one as the "*licence application*".

5.

In the licence application the Minister is cited because of her interest in the matter but no relief is sought against her. Her interests may lie therein that a possible appeal to her regarding the licence application was not pursued by the Applicant, who therefore did not exhaust an internal remedy. More about this later.

6.

The Applicant bought, imported and refurbished a certain Varian Linear Accelerator, and sold it to Cancare. This machine/unit falls under, and is regulated by the provisions of the Hazardous Substances Act 15 of 1973 ("*the Act*"). It can therefore only be imported, refurbished, sold, installed and used under a licence/licences issued in terms of the Act and the

regulations and issued by the DG. Different licences are provided for the different usages referred to above and if need be, the different entities. The conditions in each instance may also differ. In this case the Applicant had to be licensed with or without concomitant conditions to import, refurbish, sell and install the machine. Cancare, as purchaser of the machine, had to obtain a licence to use the machine i.e. a valid "*premises*" licence.

7.

It is necessary to set out the legislative background to these issues, including the definitions contained in the Act.

7.1 Section 1 of the Act contains the following definitions:

7.1.1 "*Manufacture" when used as a noun, includes assembly, production, preparation, processing, repair or any other manufacturing or maintenance process and, when used as a verb, has a corresponding meaning;*

7.1.2 *"Sell" includes offer, advertise, keep, display, transmit, consign, convey or deliver for sale, or exchange, or dispose of to any person in any manner, whether for the consideration or otherwise, or manufacture or import for*

use in the Republic; "Selling" and "Sale" have a corresponding meaning;

(my emphasis)

7.2 Section 4: Licensing

Subject to the provisions of this section the Director General may on application in the prescribed manner and on payment of the prescribed fee (if any) and subject to the prescribed conditions and such further conditions as the Director General may in each case determine, issue to any person a licence –

(a) to carry on business as a supplier of group I hazardous substances;

(b) to sell, let, use, operate or apply any group III hazardous substance;

(c) to install a group III hazardous substance on any premises mentioned in such licence."

7.3 Section 7: Suspension and cancellation of licences –

"If the holder of a licence under Section 4:

(a) has in or in connection with an application for a licence or renewal of a licence furnished the Director General with any information which to the knowledge of such holder is untrue or misleading in any material respects;

(b) has contravened or failed to comply with the conditions subject to which the licence was issued;

(c) has contravened or failed to comply with the provision of this Act;

(d) ….

(e) ……

the Director General may by way of a notice in writing call upon him to show cause within the period specified in the notice, which period shall not be less than 20 days as from the date of the notice, why the

licence in question should not be suspended or cancelled."

7.4 Section 9A: Embargo

An inspector may at any time place an embargo for an indefinite or prescribed period on any grouped hazardous substance, appliance, vehicle or other object, which is considered in or is on reasonable grounds believed by him to be concerned in a contravention or suspected contravention of any provision of this Act, irrespective of where or in whose possession he finds such substance, appliance, vehicle or object; For the purposes of this Act, "*embargo*" in relation to any grouped hazardous substance, appliance, vehicle or other object, means a prohibition on the export, sale, dumping, lease, use, operation, application, or installation of any premises, thereof.

7.5 In this context the word "***refurbish***" is used often, and it is convenient to cite the dictionary meaning thereof as found in Collins English Dictionary Millennium Edition:

"*To make neat, clean, or complete as by renovating, re-equipping, or restoring*".

8.

Applicant has at least since 1992 been importing, refurbishing and selling machines of this nature to various hospitals and other instances in this country. The issue in both these applications started when Cancare applied for a licence to use this particular machine that it had bought from Applicant. In the application for use of the machine, Cancare described it as a <u>new</u> Varian Clinac 2100 C, manufactured in 2007. It transpired later, after an inspection by one K J Smit (Smit), as representative of the DG, that the machine was in fact not new but "w*as a pre-owned unit*" manufactured in 1995 with serial number 793.

9.

On the basis of this information Smit wrote to Applicant on the 18th March 2008:

"*Notice is hereby given that an embargo has been placed on the <u>licences</u> listed below for the importation of Varian Linear*

Accelerators, with immediate effect: (a list of 12 licences are set out). This action has been taken for the following reasons:

1. *On 1 December 2007 we received an application for the installation of a <u>new</u> Varian Clinac 2100 (year of manufacture 2007 and that the unit will be supplied by Tecmed) at Durban Oncology.*

2. *Tecmed is currently licensed to import <u>new</u> Clinac 2100's;*

3. *During an acceptance inspection by K J Smit on 10 March 2008 at Durban Oncology Centre, it was established that this is a pre-owned Varian Clinac 2100 unit (date of manufacture 1994 or early 1995, serial number 791) that was imported and rebuilt by Tecmed in S.A. (this was confirmed by Mr Wegere on 11.03.2008 in my office at Louville Place Bellville);*

4. *Tecmed has therefore <u>illegally</u> imported the pre-owned Clinac 2100 and provide false information on Form RC003-1. (sic)*

The Department of Health will only consider withdrawing the embargo if:

1. *Tecmed export the Varian Clinac 2100 C (serial number 791) installed at Durban Oncology Centre, or;*

2. *Dismantle the abovementioned unit.(sic)*

Please note that under an embargo, you may not import or install any group III hazardous substances listed in the abovementioned licences. The term sell (in the) Hazardous Substances Act 1973 (Act 15 of 1973) is defined to include offer, advertise, keep, display, transmit, consign, convey or deliver for sale, or exchange, or dispose of to any person in any manner, whether for a consideration or otherwise, or manufacture or ***import for use (for own use) in the Republic*** *and the selling and sale have a corresponding meaning.*"

(**Annexure "FA2", page 57, embargo application "EA"**)

10.

This decision/action on behalf of the DG brought on an urgent appeal to the Minister in terms of the Act. The appeal was refused. Hence this application in the embargo application to have it set aside.

11.

As a result of this embargo, Cancare was for obvious reasons refused a licence to use the machine, hence the licence application.

12.

It will be noted that in both instances Applicant is not the end user of the machine, but only the seller/supplier thereof and installer to Cancare. Both applications started as urgent applications in the middle of last year (between May and July 2008), but were struck off due to lack of urgency. The whole issue of urgency has fallen away and only the merits are at issue at this stage. The Minister and the DG initially disputed Applicant's *locus standi* to bring this application. This point was not pursued in argument and I think rightly so. The definition of an "*interested party*" in the Act is so wide it must include the Applicant in the circumstances prevailing here.

13.

As for the licence application, a further point was taken by the DG: that Applicant did not exhaust all internal remedies. Applicant's answer to this is that it would have served no purpose because the Minister had already

made up her mind and decided with regard to the embargo appeal. It must be axiomatic that while that decision stands there is no way in the world that she could or would have granted a licence to Cancare to use the machine. For that simple reason Applicant's application for condonation for not following the internal appeal route, must succeed, an order which I hereby grant.

14.

A further issue that needs to be addressed is the fact that Applicant in the licence application, filed a supplementary affidavit, stating simply that further developments had taken place since finalisation of the papers and attach certain documents and correspondence that were exchanged between the parties. The Minister and the DG objected to the admission thereof since:

14.1 No condonation was sought for the filing of same;

14.2 The intention for filing it and more particularly, the inferences and facts to be deduced there from were not set out. Neither were the Respondents invited to answer thereto.

15.

The application in terms of Rule 30 for striking out of the supplementary application as an irregular proceeding, did not reach me prior to the hearing of these applications. I did, however, on the morning before the hearing, have an opportunity to read same. It was eventually agreed by all that the supplementary documents could stay in, and, as and when any reference thereto is made, the specific document will be discussed and handled at that stage.

16.

It is, however, convenient to deal with those documents directly. As evidenced from the letter quoted above, the DG put an immediate embargo on the Applicant in respect of the twelve listed licences, which obviously included the one relating to the machine at issue. In terms of Section 7, a licence can only be revoked or suspended on 20 days' written notice. In terms of Section 9A of the Act an embargo can only be imposed upon a "*Grouped Hazardous Substance, appliance, vehicle or other object".* It does not include a "*licence*", because that is clearly dealt with in Section 7. Clearly and on the face of it this was an illegal embargo, because Applicant was not given 20 days to object to either a suspension or revocation, and neither could a licence be embargoed.

17.

In spite of these issues being clearly set out in the appeal to the Minister in the embargo application, the appeal failed.

18.

This is where the supplementary affidavit of the Applicant becomes relevant. Since the documents speak for themselves, it is important that cognisance must be taken thereof and I overrule the objection in respect of the documents. I shall refer to them later. The reason is that they go to the very heart of the embargo application. The relevant documents show the following:

18.1 On 05.08.08 Smit writes to Applicants stating as follows:

> "*Our letter dated 18 March 2008 considering the embargo on the importation of Varian Linear Accelerators refers.*
>
> *Notice is hereby given that the embargo that was placed on the importation of Varian Linear Accelerators, dated 18 March 2008, has been*

withdrawn with immediate effect." (**Annexure "SA2", p 318, licence application ("LA").)**

18.2 On the same date, i.e. 5/8/08, Smit again places an embargo, this time on 14 Varian Clinac machines. It is stated that the embargo will only be lifted if Applicant exports the machine. (No reason is given why all the other machines are also embargoed!) (**Annexure "SA3" page 319 "LA"**).

18.3 On 16.10.2008 Smit again writes to Applicant giving notice of the intention to suspend licence number 140/2233 in terms of Section 7(1) of the Act. Applicant is called upon to show cause within 20 days of date of the letter why the licence should not be suspended (**Annexure "SA9" page 346 "LA"**).

18.4 On 17.11.2008 Applicant's attorney files an answer objecting to the intended suspension (**Annexure "SA10", page 347).** To date, as far as I know, no decision has as yet been taken.

19.

EMBARGO APPLICATION:

The Applicant's contention regarding this issue was that the DG was not in law entitled to issue the embargo in respect of licences. He could only do so in respect of objects, etc. If he wanted to stop the importation or selling of machines he had to give notice in terms of Section 7 with 20 days' notice. He did none of this. The embargo was thus illegal. The DG realised this himself eventually when a proper notice was given in respect of certain licences as referred to already, and he withdrew the abovementioned embargo.

In respect of the appeal to the Minister the same issues were raised by Applicant but the appeal was still refused by the Minister. This clearly shows that the embargo application must at least to that extent succeed.

20.

LICENCE APPLICATION

The issue here turns on the question of what licence conditions obtained at what time, and whether the specific machine was imported legally or not. It is therefore important to analyse the various conditions that applied at various times.

21.

On 4.04.2001 the licence to sell was issued to the Applicant in terms of Section 4(1)(b). The relevant condition read as follows:

> "*A licence to sell this model only permits the sale of refurbished units by the approved dealer, i.e. it does not permit the sale of either new units or used units that have <u>not been</u> refurbished.*
>
> (**Annexure "B", p 231, LA).**
>
> This thus meant that the Applicant could import, refurbish (i.e."manufacture"), sell and install such a machine.

22.

On 21 June 2001 new conditions were imposed. The new condition read as follows:

> "T*he licence to sell this model only permits the sale of new units by the approved dealer, i.e. it does not permit the sale of either refurbished units or used units that had <u>not</u> been refurbished. The definition of "sell" includes offer, advertise, keep, display, transmit, consign, convey or delivery for sale, or exchange, or dispose of to any person in any manner, whether or consideration or otherwise, or*

manufacture or import for the use in the Republic of South Africa; and selling and sale have a corresponding meaning."

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23.

This condition is somewhat ambiguous. On the one hand it only permits the sale of new units by an approved dealer, but it does not permit the sale of either refurbished units or used units that have not been refurbished. It would therefore seem as if refurbished units may be sold. This is a restrictive condition and therefore must be interpreted restrictively as well. It therefore seems that a refurbished unit whether old or new, may be sold (with all the *sequeulae* pertaining to the definition of the term "*sell*", if refurbished.) Therefore Applicant was entitled to import and refurbish and sell the units.

24.

On 30.10.2001 the Director of Radiation Control sent a copy of the group licence to Applicant, as at that date. **See: Annexure "FA5.2" at page 83**

EA. No specific reference is made therein to the condition of 11.06.2001. It only states that certain certifications must be provided.

25.

On 11.10.2005 new conditions were published and sent to the Applicant. In terms thereof, the Applicant had until 01.11.2005 to supply certain certificates to the Department relating to any unit falling under the said licence.

From the importation documents (attached to the embargo appeal to the Minister) the following history regarding importation of the unit can be gleaned.

25.1 The supplier's invoice is dated 15.08.2005; **page 108/EA**);

25.2 The "*arrival notice*" at Durban Harbour is dated 07.10.05, **page 110 EA;**

25.3 "*Customs release notification*" is dated 13.10.05 (**page 105/EA**);

25.4 The City Deep Terminal Manager's stamp (Johannesburg) is dated 14.10.2005.

26.

From the above it is clear that the unit was bought and imported into South Africa before the new licence conditions applied and the requisite certificates had only to be supplied by 01.11.2005. It is so that Applicant's deponent states in the affidavit supporting the appeal to the Minister that the unit was imported on 28.10.2005. However, that is a reference to the "*tax invoice*" delivered to Applicant by the cargo carriers (**FA6, page 102 EA)**. The documents referred to in paragraph 26 above are all part of **Annexure "FA6"**. Deponent refers to them as "*the importation vouchers*". It is therefore clear that the actual importation occurred prior to the date of the conditions.

27.

From the above and reading the provisions of the Act, the relevant conditions and the importation documents all together, it is clear that the relevant unit was <u>not</u> imported illegally as alleged by the DG and the Minister. It is therefore clear that the imposition of the embargo (already dealt with) and the refusal to grant a licence for the installation and use

thereof at Cancare was unlawful, it being the main reason to refuse the licence.

28.

Another ground for refusing the licence is that Applicant is only allowed to import new and refurbished machines. (Respondents' heads of argument, para 18.1). the Respondents' attitude is that Applicant needs to be licensed as a manufacturer to do so. However, when one reads the definition of sell and/or manufacture and the dictionary meaning of refurbished, it is clear that as it stands, the licence to sell includes manufacture (the nouns and verbs have corresponding meanings in terms of the definitions section). It is difficult to see how the restrictive meaning proposed by the Respondents fit into those definitions. This point can therefore not succeed.

29.

The next issue that arose is the question of the certification by European standards of the Applicant to refurbish machines. Smit was initially satisfied with the certification provided to him. However, the Respondents now maintain that the "EC" (European Community) certification issued to Varian, the manufacturer, in terms of the specific models, is not sufficient

for purposes in South Africa. Applicant must be directly *in eo nomine* issued with the EC certificates as a "*manufacturer*".

30.

From the facts set out on behalf of the Applicant in the appeal, which were never specifically answered or disputed by the Respondents, he sets out clearly the history of the importation of the machine. After the importation in 2005 the machine was stored. In 2007 Applicant did the refurbishing and sold it to Cancare. On 11.12.2007 Cancare was issued with a licence to install the machine. This must obviously be a licence to use the machine because only the premises need to be licensed for use. This was issued on the basis that it was a <u>new machine</u>. Subsequently this licence was not actually issued, or withdrawn, it is not clear which. The reasons are set out by Smit in an e-mail to Ms Hester Burger of the Durban Oncology Centre dated 11.03.2008. It reads as follows:

> "*The situation with regard to the licensing of Varian Clinac 2100 at Durban Oncology is as follows:*
>
> *1. On 5th December 2007 we received an application for the installation of a Varian Clinac 2100 (year of*

manufacture 2007 as well as that it is a new unit that will be supplied by Tecmed) at Durban Oncology;

2. *A licensed was issued on the 11 December 2007 for the installation of the above, based on the assumption that this is a new unit;*

3. *Tecmed is currently licensed to import new Clinac 2100's. To obtain a licence for importation, the importer must submit documentation as specified in 41BM-1;*

4. *Tecmed has therefore illegally import (sic) the pre-owned Clinac 2100, and under these circumstances the Department of Health will not issue a licence for use;*

5. *We will demand that this unit be exported or be sold off as scrap;*

6. *……*

As already pointed out it was not a new machine but simply wrongly described by Cancare in the application for a licence to use it. That was cleared up and as shown above, the machine was not illegally imported.

32.

Since then the Department has also consistently required EC certification of the Applicant itself. On 23.08 Applicant gave the DG copies of Varian's EC accreditation and also Applicant's appointment as fully accredited agent of Varian (**Annexure "FA17", page 162 EA**). The latter states the following in the second paragraph:

> "*Refurbishing Agreement is in place as of 03.08.2007 and covers all Quality and Regulatory provision being part of all Varian products and comply with the US, Code of Federal Regulation (CFR) and Euro Norms (CE) and all applicable aspects of US FDA and EN/ISO regulation guidance and precedent.*" (**Annexure "FA17", p 163 EA**).

This letter is addressed to the Applicant and sent by Varian Medical Systems and dated 27 September 2007.

33.

When one looks at the licence requirements set by the Respondents it requires the licence holder's EC certification. The question is whether an agent is included under such certification.

34.

This question must also be viewed in the light of the surrounding circumstances and facts. Initially the DG refused Cancare's licence because the unit was allegedly imported illegally. This attitude was relinquished. Then it requested EC certification to be supplied by 1 November 2008. In an e-mail to the Applicant on 9.04.2008 (**Annexure "F22", page 174, EA**) Smit now states that unless the certification is provided by 16.02.2007 (sic it must be 2008), the licence will be cancelled. This is obviously an illegal demand in terms of Section 7 of the Act (where 20 days' notice must be given of an intention to cancel). This clearly contradicts the 1 November 2008 deadline. It can therefore not be a legal demand.

35.

In the light of all that has happened regarding this machine it is clear that the Department acted illegally and unlawfully. The embargo was illegal and the threat to cancel the licence in April 2008 was illegal. This all prompted two urgent applications which were refused initially for want of urgency. However, having considered the merits as set out above, both applications must succeed, because the deadline of 1/11/08 only expired after these applications were issued.

36.

It is common cause that costs should follow the result in both cases. The only question is whether the Applicant is entitled to the costs of two counsel. Respondents had a single senior/junior advocate. She said that if she could handle it alone, so could Applicant's counsel. However, when one looks at the volume of the two applications and the detail that had to be unravelled, it points to the use of two counsel. Then there is the importance of the matter to the Applicant. It is uncontested that the use of the machine is not only worth many thousands of rands to the Applicant but the machine itself is worth a few hundred thousand rands. It is also

obviously of great importance to Cancare and more importantly to the patients needing the treatment. It is undenied that this machine is a very good and useful machine in cancer treatment. In fact it is undeniably a life saving unit.

37.

In the light of the above the costs of two counsel are justified.

38.

I therefore make the following orders:

In application 25382/08

1. the decision of the First Respondent dated 23 May 2008 in respect of the appeal to her by the Applicant dated 5 May 2008 in terms of Section 6 of the Hazardous Substances Act, 15 of 1973, is reviewed and set aside;

2. The appeal by the Applicant to the First Respondent dated 5 May 2008 in terms of Section 6 of the Act is upheld;

3. First Respondent is to pay the costs of the application including the costs of two counsel.

In application 30841/2008

1. The Applicant is exempted from any obligation it may have had to exhaust any internal remedies as provided for in Section 7(2) of the Promotion of Administrative Justice Act, Act 3 of 2000.

2. The decision by the First Respondent to refuse to issue the Second Respondent a licence to us a Group iii Hazardous Substance in terms of the Second Respondent's application dated 15 March 2008 is hereby reviewed and set aside

3. Respondent is to pay the costs of the Applicant, including the costs of two counsel.

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R D CLAASSEN
Judge of the High Court