IN THE HIGH COURT OF SOUTH AFRICA

Delete whichever is not applicable

(1) Reportable Yes / No
(2) Of interest to other Judges Yes / No
(3) Revised.

Date: 12 June 2014

Signature.....

GAUTENG DIVISION, PRETORIA

12/6/2014

In the matter between:

GELDERMA LABORATORIES SOUTH AFRICA

(PTY) LTD Applicant

and

MEDICINES CONTROL COUNCIL First Respondent

DIRECTOR GENERAL OF THE NATIONAL

DEPARTMENT OF HEALTH Second Respondent

MINISTER OF HEALTH Third Respondent

ALLERGAN PHARMACEUTICALS (PTY)	Fourth Respondent
LITHA PHARMA (PTY) LTD	Fifth Respondent
CONQUEST SURGICAL SUPPLIES (PTY) LTD	Sixth Respondent
GLENMARK PHARMACEUTICALS SOUTH AFRICA (PTY) LTD	Seventh Respondent

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J U D G M E N T

Ismail J:

[1] During the course of this judgment the parties will be referred to Interchangeably as the applicant or Gelderma; the first respondent or ' MCC'; the second respondent or 'the DG' ; the third respondent or 'the Minister'

[2] This application is opposed by the first to the third respondents. They are collectively referred to as the ' government respondents'.

[3] The fourth to seventh respondents have not opposed the application. They have for convenience been referred to as 'the competitors' of the applicant. No order is sought against them.

[4] The applicant seeks an order declaring that:

(1.1) Medical devices as defined in section 1 of the Medicines and Related Substance Act 101 of 1965 ("The Medicines Act") are not subject to registration in terms of section 14(2) of the Medicines Act

(1.2) in absence of the promulgation of appropriate regulations in terms of section 35(1) xxvii) of the Medicines Act the first respondent and / or the second respondent are not empowered to deal with authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation exportation, storage, transportation, sale or use of any medical device or class of medical devices in respect of its safety, quality and efficacy in the Republic;

(1.3) The product identified in annexure "FA1" to the founding affidavit ("the Restylane products") as emanating from the applicant are medical devices as defined in section 1 of the Medicines Act;

(1.4) The Restylane products are accordingly not subject to registration in terms of section 14 (2) of the Medicines Act.

(2) Such parties who oppose this application are ordered to pay the costs of this application, including the costs of two counsel;

(3) further and/ or alternative relief

Background

[5] On 5 February 2012 , the Port authorities detained a consignment of the applicant's dermal fillers imported for sale within the country. The first respondent was of the view that these products were not registered in

terms of section 14 of the Act.

[6] The first respondent addressed a letter to applicants attorneys dated 17 April 2013 wherein it stated:

" Please be informed that we have perused the above mentioned letter and considered the submissions set out therein.

We reiterate that local anaesthetics fall under pharmacological classification 4, category In terms of the regulations promulgated (sic) Government Notice R2025 of 15 December 1967.

Please take further note that local anaesthetics have been called up for registration in terms of call up notice of 5 July 1988. Thus, your product, Restalyne Filler with Lidocaine is subject6 to registration in terms of section 14(2) of Medicine and Related Substance Act of 1965 (Act 101 of 1965).

[7] Applicant's attorneys addressed a letter to the registrar of the first respondent dated 24 April 2013 wherein they stated the following:

" 3. We wish to emphasise again that, although a schedule substance, lidocaine supports, as per definition of medical devices In the medicines Act, the operation of the device. In this instance the product contains 0,3% of lidocaine, a miniscule amount that would not even be detectable in the patient's system after administration."

[8] The applicant approached this court in order to obtain finality on the classification of its dermal filler product range sold under the brand name Restylane (the Restylane products). The issue to be determined is whether the Restylane products and in particular those containing Lidocaine, are medicines in terms of the Medicines and Related Substances Act 101 of 1965 (the Act).

[9] This set in motion the present proceedings before court. Not intending to oversimplify the issue between the parties it appears that the question which needs to be determined is whether the dermal fillers containing lidocaine is a medical device as the applicant's contends or whether it should be registered because it contains a substance which is registrable.

[10] It would be prudent for the purpose of a proper understanding of the matter if I were to set out what is defined as a "medicine" and what a "devices" has been defined as in terms of the Act.

The term "medicine" has been defined as follows:

" means any substance or mixture of substances used or purporting to be

suitable for use or manufactured or sold for use in-

(a) The diagnosis, treatment mitigation, modification or prevention of disease, abnormal physical or mental state or the symptom thereof in man; or

(b) restoring, correcting, or modifying any somatic or psychic or organic function in man,

and includes any veterinary medicine;

A "medical device" has been defined a:

Means any instrument , appliance, material, machine, apparatus, implant or diagnostic reagent-

(a) used or purporting to be suitable for use or manufactured or sold for use in-

(i) the diagnosis, treatment, mitigation, modification, monitoring or prevention of disease, abnormal physical or mental states or symptoms thereof;
or

(ii) restoring correcting, or modifying any somatic or psychic or organic

function; or

(iii) the diagnosis or prevention of pregnancy,

and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by means; or

(b) declared by the Minister by notice in the Gazette to be a medical device;,

Legal Submissions made

[11] Mr Maleka SC acting for the government respondents submitted during argument before me that the applicant choose to bring this application and it sought a declarator. The applicant could therefore not argue on the facts as there was no record. Had it brought the application by way of review or in term of Rule 53 there would have been a record of what decisions were taken and the facts could be gleaned from the record.

As opposed to this argument Mr Unterhalter SC submitted that the applicant could elect to bring a dispute to court by various means. It chose to bring its case in this manner and it therefore had to make out its case in

order for it to succeed otherwise it would fail. He submitted that nothing precluded the applicant to seek relief in the manner it sought.

[12] Permit me to thank the parties for their input in this matter and more particular for the helpful and informative heads of arguments presented. The court is grateful to both parties and would 'borrow' from their input where necessary.

[13] The applicant's attorneys addressed a letter to the registrar of the first respondent wherein the following was stated at paragraphs 6 and 7:

" 6 This dispute can only be determined by the Courts. Our client has instructed us To bring proceedings for declaratory relief so as to secure finality and certainty as to whether our client's device (and devices that compete with it in the South African market) is subject to registration.

7. Pending the Court's decision, our client will continue to trade in the market in accordance with its view of the law. Needless to say, if the Courts should determine the matter against our client, our client will comply fully and promptly with the law"

In response to this letter the respondents relied upon Prof Hoek's findings

and in the answering affidavit at paragraph 8.6 the deponent Dr Khomo stated the following:

" On 6 August 2013 Prof B Hoek came to the following conclusion and recommended to council: ....

At para 8.7 of the same affidavit the following is stated:

" Because of the side effects and uncertainty regarding their safety and efficacy of repeated use of these products (which contain hyaluroric acid, with or without lidocaine) as well as the fact that the First Respondent has registered some other hyaluronic acid products, the First Respondent regards the injectable dermal fillers gel as medical products for registration purposes"

[14] When the first respondent received the applicants letter dated 6 April 2013 (FA 2.77), a four page letter, it responded thereto by a letter referred to in para [5] , supra. This response it appears was based on a finding made by a clinical committee under the auspicious of Prof Hoek from the University of the Free State. The committee recommended to the first respondent that the applicant's product should be registered as a medicine.

[15] Prof B B Hoek's expertise in the field of dermal filler's was questioned by the applicant who averred that he is a paediatrician and not a dermatologist and thus not an expert in skin related matters. The applicant, on the other hand, relied on the view of Per Goran Heden, a doctor of Medicine and a doctor of Philosophy in Plastic Surgery; licensed specialist in Plastic Surgery in Sweden and United Kingdom; Associate Professor in Plastic Surgery at the Karolinska Institutet and the founder and head of the Akademikliniken, the largest private hospital specialising in Plastic and Reconstructive Surgery in Scandanavia. (his affidavit appears at pages 778-787 of the papers). In his affidavit at paragraph 6 he deposed that:

" I have been requested by Gelderma Laboratories south Africa (Pty) ltd (Gelderma) to consider the definition of a "medical device" as defined in section 1 of the Medicines and related Substances act No 101 of 1965 ("the Medicines Act) and to express my opinion, based on such definition whether the Restylane products fall within the definition of a "medical device" or not."

At paragraph 17.6 of the affidavit he concluded :

" 17.6 Results of my investigation using restylane products containing lidocaine from a Prospective clinical study have been published in peer- reviewed journal and the data provide conclusive evidence that the small amount of lidocaine is added for patient comfort during injection, without any impact on the purpose of these Restyulane products containing lidocaine and these Restylane products are medical devices.

independent expert investigators have come to similar results and conclusions (Brandt F and Bank D 2010)

[16] It was submitted on behalf of the applicant's that Dr Heden's expertise in the field was not challenged. This was conceded by Mr Maleka during argument before me.

[17] Mr Unterhalter submitted that the fact that Prof Hoek's committee recommended to the first respondent that the dermal fillers should be registered as a medicine.

The resolution must be approved by council and it is only the Minister who can regulate that it be registered as a medicine. This argument was further developed to the extent that the recommendation of the committee consisting of Prof Hoek, was at best a recommendation of the clinical committee.

At page 209 of the papers, an e-mail sent from the Law enforcement Manager to Ms Keyser the following appears:

"According to the clinical committee of the MCC, they are of the opinion that the product should be registered in terms of section 14(2) of the Medicines and Related Substances

Act, 1965. Their decision was based on the information which was provided by you".

Absent any evidence that the Minister was approached to consider the recommendation, it was at best a recommendation and / or an opinion and nothing else. Furthermore, the applicant's product has not been called up for registration. It was submitted that there was no argument that the product was a filler, nor was there any attempt in the answering affidavit attacking the applicant's expert regarding his findings of the product.

[18] In view of the Minister not having ratified or approved the recommendation there was nothing calling for the setting aside of the regulation and therefore the *Oudekrall* principle applied.

[19] On behalf of the applicant's it was suggested that there was a serious inconsistency on the part of the respondents. In that the letter dated 7 March 2013 stated that they took a decision regarding the applicants products whereas at page 862 para [8.6] of the record the deponent deposes to Prof Hoek arriving at a decision and making recommendations on the 6 August 2013. It was submitted that this was to say the least not possible.

[20] Section 14(2) of the Act stipulates:

(2) (a) the council may from time to time by resolution approved by the Minister, determine that a medicine or class or category of medicine or part of any class or category of medicine mentioned in the resolution shall be subject to registration in terms of the Act.

(b) Any such resolution may also relate only to medicines which are available for sale in the Republic immediately prior to the date on which it comes into operation in terms of paragraph (c) or only to medicines which are not then so available.

(c) Any such resolution shall be published in the Gazette by the registrar and shall come into operation on the date on which it is so published.

[21] The applicant's product has not been called up for registration and at best the product was recommended by Prof Hoek's clinical committee that it be registered. There is no evidence that the Minister or Council itself approved of the recommendation of the committee. The fact that the substance is injected and that it has a minute amount of lidocaine which is a registered substance does not make the device a medicine. The substance injected "does not achieve its purpose through chemical,

pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by means .."

The Lidocaine only assist to the extent that it allows the patients comfort and is not part of the formulation designed to improve skin hydration, as described by Dr Heden in para [17.4] of his affidavit.

It was submitted on behalf of the applicant that the mere fact that Lidocaine is called up for registration does not mean that the device is registrable.

[22] The respondents in their heads raised the point that the applicant should have come to court by way of PAJA or they should have exhausted the internal remedies by appealing the decision . they should have followed the appeal procedure. This aspect was to an extent addressed in para [11] , supra.

Mr Unterhalter relied upon the matter of *Treatment Action Committee v Raath and Others* [2008] 4 All SA 360 (C) and to para [62] thereof, where the court stated:

"[62] The question for determination is whether VitaCell is subject to registration as a medicine. . The answer to this question will turn on the interpretation of the 2002 call up

notice. I agree with Mr *Budlender's* submission that it is not for the MCC to decide whether the substance is a medicine. It is for the courts to decide that question. But it is correct for the MCC to resolve that any particular substance requires to be registered. nature of a substance requires to be registered. The term "medicine" is defined in the Medicines Ac and if there is a dispute about the nature of the substance it is for the courts to make a determination whether or not a particular substance is a medicine as defined in the Medicines Act ".

[23] Mr Maleka submitted that there was extensive communication between the parties before the decision was made, to have the product registered as a medicine.
Firstly there was an evaluation of the product by the committee and thereafter a decision was taken. He therefore submitted that a review ought to have been brought as the court would then have had the record before it, in order to determine the factual situation. By seeking a declaratory order instead of a review the applicant cannot rely on a factual situation but only on a legal matrix.

[24] He submitted that there was a decision taken by council based on the opinion of Prof Hoek. The opinion of Prof Hoek was relied upon by Council who informed the applicant that its dermal fillers were subject to registration. It was suggested that the first respondent took a decision that

the applicants dermal fillers should be registered in terms of the Act. Accordingly first respondent advised Port authority not to release applicant's products which were subject to registration.

[25] Mr Maleka relying on the extract quoted in the *TAC* matter, at para [22], supra, submitted that the court accepted that whether a product is subject to registration in terms of the Act is one for the first respondent to determine. This he submitted was not surprising since the registration of a substance is within the purview of the first respondent to protect the unsuspecting public who are unaware of the composition and true nature of such products or substances.

The first respondent is of the view that the applicant's dermal fillers which containing Lidocaine is subject to registration in terms of section 14(2) of the Act

Maleka submitted that these dermal fillers contain Lidocaine which is a local anaesthetic. Lidocaine is used to reduce pain in the area of the skin where the dermal filler is administered. This local anaesthetic was one of the 'main barriers ' to the use of dermal fillers.

[27] Counsel for the first respondent also submitted that the applicant chose the wrong route in coming to court by seeking a declarator. He alluded to the fact that the applicant should have exhausted the internal remedies available to it, namely to appeal the decision of the MCC or sought a review in terms of PAJA. In this regard he alerted the court to the the matter of *Road Accident Fund v Duma and others* 2013 (6) SA 9 SCA dealing with the issue of serious injury for general damages. At paragraphs [18] and [19] Brand JA stated:

" [18] Consideration of the high court's judgments in the four cases on appeal and those upon which they rely, all seems set out from the premise that it is ultimately for the court to decide whether the plaintiff's injury was 'serious' so as to satisfy the threshold requirement for an award of general damages. Proceeding from that premise, these decisions assume that if the Fund should fail to properly or timeously reject an assertion to that effect by the third party, the rejection can be ignored. If the medical evidence before the court then shows that, on a balance, the plaintiff was seriously injured, the court can proceed to decide the issue of general damages.

[19] That approach, I believe, is fundamentally flawed. In accordance with the model that the legislature chose to adopt, the decision whether or not the injury of a third party was serious enough to meet the threshold requirement for an award for general damages was conferred on the Fund and not the court. That much appears from the stipulation in reg 3(3) (c) that the Fund shall only be obliged to pay general damages if the Fund- and not the court- is satisfied that the injury has correctly been assessed in accordance with the RAF 4 form as serious....."

[28] It was submitted by counsel that the court should be slow in exercising its discretion in granting the declaratory orders which the applicant seeks as the MCC considered the issue of the applicant's product and acted in the public interest. For that reason it was a decision for the MCC to make, whether the product is a medicine or not and not for the court to determine.

[29] *Cora Hoexter* in her book *Administrative Law in South Africa* dealing with declaration of rights at pages 493/4 states:

" As the name suggest, a declaration of rights (also known as declaratory orders) enables a court to declare the right of the parties or to state the legal position.

The writer continued and referred to what O 'Reagan J in *Rail Commuters Action Group v Transnet Ltd t/a Metrorail* 2005 (2) SA 359 (CC) at para [107] said:

" [107] it is quite clear that before a court makes a declaratory order a court must consider all the relevant circumstances. A declaratory order is a flexible remedy which can assist in clarifying legal and constitutional obligations in a manner which promotes the protection and enforcement of our constitution and its values. Declaratory orders, of course, may be accompanied by other forms of relief, such as mandatory or prohibitory orders, but may also stand on their own. In considering whether it is desirable to order mandatory or prohibitory relief in addition to the declaratory, a court will consider all the relevant circumstances."

This paragraph should be read in conjunction with what was stated in para [11], supra.

[30] The applicant also seeks an order declaring that:

" 1.2 in the absence of promulgation of the appropriate regulations in terms of section 35 (1)(xxvii) of the Medicines Act the first respondent and/or the second respondent are not empowered to deal with the authorizing, regulating, controlling, restricting, or prohibition the registration, manufacture, modification, importation, exportation, storage, transportation, sale or use of any medical device or class of medical device in respect of its safety, quality and efficacy in the Republic "

Mr Maleka submitted that the court in the exercise of its discretion should not grant such an order as the first respondent has taken a decision. Mr Unterhalter on the other hand submitted that if the respondents want to have the applicants product declared a medicine they should invoke the provisions of section 35 of the Act which authorizes the Minister in consultation with council to make regulations.

This procedure has not been followed and at best a recommendation was made to council by the investigative committee in the absence of the Minister having been involved in the process.

[31] The Act in terms of section 35 has a built in procedure for making regulations in terms of section 35. It was submitted that if the intention was to promulgate regulations restricting or controlling a device it should regulate it as such in terms of the section. This procedure has not been followed.

[32] For the reasons set out above I am of the view that the following will be an appropriate order.

(1) in absence of the promulgation of appropriate regulations in terms of section 35(1) (xxvii) of the Medicines Act the first respondent and / or the second respondent are not empowered to deal with authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation exportation, storage, transportation, sale or use of any medical device or class of medical devices in respect of its safety, quality and efficacy in the Republic;

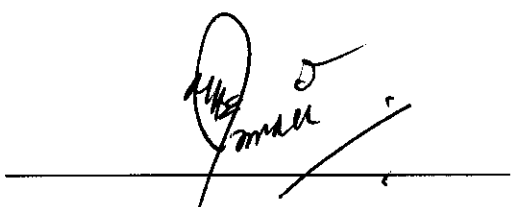
(2) The product identified in annexure "FA1" to the founding affidavit ("the Restylane products") as emanating from the

applicant are medical devices as defined in section 1 of the Medicines Act;

(3) Restylane products are accordingly not subject to registration in terms of section 14 (2) of the Medicines Act.

(4) The First, Second and Third respondents are jointly and severally ordered to pay the applicants costs. The one paying the others are absolved.

Such costs to include the costs of two counsel.



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APPEARANCES:

For the Applicant: Adv D Unterhalter SC assisted by Adv A C Botha instructed by Goldman Judin Inc, Johannesburg c/o Savage Jooste & Adams, Pretoria

For the First, Second & Third Respondents: Adv V Maleka SC assisted by Adv M.S Mphahlele instructed by The State Attorneys, Pretoria.

Date of Hearing: 12 May 2014

Judgment delivered: 12 June 2014.