JMLS

JAMAICA

IN THE COURT OF APPEAL

SUPREME COURT CIVIL APPEAL NO. 101/98

BEFORE: THE HON. MR. JUSTICE DOWNER, J.A.
THE HON. MR. JUSTICE PATTERSON, J.A.
THE HON. MR. JUSTICE LANGRIN, J.A.

BETWEEN	HEALTH-PRO (JAMAICA) LTD.	APPELLANT
AND	THE ATTORNEY-GENERAL OF JAMAICA (for the Minister of Health)	RESPONDENT

B. Veronica Warren for the Appellant
Cheryl Lewis Crown Counsel for the Respondent
instructed by the Director of State Proceedings

April 13 - 14 and July 30, 1999

DOWNER, J.A.

Ms. Warren moved the Supreme Court, (Ellis, Panton Granville James JJ) for an order of Mandamus to compel the Ministry of Health pursuant to the Food and Drugs Act the 1975 Regulations thereto to issue the appropriate licence to advertise for sale without the restrictions imposed by the Minister. The drug in issue is sold under the name Pycnogenol. The applicant Health Pro Jamaica Ltd. was aggrieved by the order of the Supreme Court's refusal to issue the order for Mandamus so they have sought redress in this Court. There is also a claim for damages which is impermissible in these proceedings so it will not be considered.

To appreciate the nature of the applicant's claim reference must be made to Section 3 of The Food and Drugs Act. That Section reads:

> "3.-(1) A person shall not advertise any food, drug, cosmetic or device to the general public for the treatment, prevention or cure of any of the diseases, disorders or abnormal physical states mentioned in the First Schedule.

> (2) A person shall not sell any food, drug, cosmetic or device -
> (a) that is represented by label; or
> (b) that he advertises to the general public,
> for the treatment, prevention or cure of any of the diseases, disorders or abnormal physical states mentioned in the First Schedule."

The substance of the claim was formulated thus:

> "(a)That the Minister of Health has seriously hampered and restricted the Applicant in its marketing and sale of the new drug, Pycnogenol, by preventing the Applicant from advertising the therapeutic benefits of the new drug in accordance with the use for which it is imported into Jamaica under the Food and Drugs Act and Regulations."

It was against the background of the above that Mrs. Grace Allen Young was reported in the **Daily Gleaner** of April 2, 1997, as follows:

> "According to Grace Allen Young, director of the Pharmaceutical Services Division at the Ministry of Health, the advertisers of the product had committed breaches of the Food and Drugs Act 1964 and the Food and Drugs Regulations 1974.
>
> She explained that all drugs or supplements whether they be registered, over the counter or registered prescribed, should be approved by the Pharmaceutical Services Division.
>
> In addition, all advertisements of the product must be approved by the Ministry before placing it with the media. She argued that the advertisement placed was also in breach of section three, paragraph one of the Food and Drugs Act which states that "A person shall not advertise any food, drug, cosmetic or device to the general public for the treatment, prevention or cure of any of the diseases, disorders or abnormal physical states mentioned in the First Schedule". The schedule includes Cancer and Cataract diseases which were mentioned in the advertisement."

As for the regulation dealing specifically with advertisements Regulation 4(1) reads:

> "A person shall not advertise any food, drug, cosmetic or device to the general public for diseases, disorders or abnormal physical states mentioned in the First Schedule.

Please note that the licence referred to in Regulation 64 is limited to "the importing, sale or manufacture, as the case may require, of that new drug.

The affidavit dated 14th October, 1997 of Leslie Giscombe an executive of the appellant company shows how the dispute arose. Here are some extracts:

> "(2) That in or about December, 1995 Health Pro International Inc. made an application to the Minster of Health through the Pharmaceutical Services Division of the Ministry of Health for a licence to import, sell and advertise for sale a new drug named 'Health-Pro Pycnogenol', which is an antioxidant in tablet form. The licence was granted by letter dated March 22, 1996."

Here is the Registration or licence:

> "Kabco Inc
> 2000 New Horizon Boulevard
> Amityville, NY 117735
>
> Dear Sirs:
>
> RE: REGISTRATION OF PHARMACEUTICAL PRODUCTS MANUFACTURED BY: KABCO INC. USA.
>
> This is to inform you that the following herbal product with its Corresponding registration numbers has been registered under the FOOD & DRUGS ACT 1964 as of March 18 1996,
>
> The formulations submitted in support of the application has been placed on our records.
>
> | PRODUCT | REGISTRATION NUMBER |
> |---|---|
> | HEALTH-PRO PYCNOGENOL ANTI-OXIDANT TABLETS 20MG | 19A 5 |
>
> Yours sincerely:
> PHARMACEUTICAL SERVICES DIVISION.

Then admitting that there was an advertisement he states:

> "8) That on March 25, 1997 the Applicant advertised pycnogenol in the Daily Gleaner stating some of its

therapeutic benefits. Attached hereto and marked 'LG2' for identification is a copy of the advertisement."

No approval was sought or obtained for this advertisement. Then the dispute is emphasised thus:

9) On April 2, 1997 the Minister of Health published an article in the Daily Gleaner headlined 'Food supplement ad spurs Ministry action." In the article the Minister through his servant or agent publicly charged that Health-Pro Ja. Ltd. had inter alia breached section 3(1) of the Food and Drugs Act. He wrote as follows:

> 'A person shall not advertise and food, drug, cosmetic or device to the general public for the treatment, prevention or cure of any of the diseases, disorders or abnormal physical states mentioned in the First Schedule.' 'The Schedule includes Cancer and Cataract - diseases which were mentioned in the advertisement. From all indications, they have breached the Food and Drugs Act on two counts and so we are going to take action.'
>
> The Minister of Health did not at any time before publication of this article threatening legal action, notify Health-Pro of any objection to the advertisement or of any objection of any sort whatsoever. Attached hereto and marked 'LG3' for identification is a copy of the said news paper article.

10) That when the Applicant herein advertised the new drug for sale on March 25, 1997 it did so in accordance with the therapeutic use for which the new drug is imported into Jamaica under the Food and Drugs Act and Regulations. Nevertheless since April 1997 the Minister of Health has objected to and prevented the applicant from continuing to advertise in accordance with its legal entitlement. As a result the applicant is being severely restricted in its business and is suffering damages'."

At this point it is necessary to cite the provisions dealing with registration Regulation 40(1) reads:

> "40.-(1) A person shall not sell, manufacture, import or distribute a drug unless -
>
> (a) that drug has been registered with the Ministry of Health; and

(b) a fee of $25.00 has been paid in respect of such registration

(2) The Minister may, in his discretion, exempt any person or any drug from the requirements of paragraph (1).

Then Regulation 64 defines "new drugs" and regulation 65 in part states:

"65.-(1) A person shall not import, sell, advertise for sale, or manufacture, a new drug unless -

(a) he has been issued a licence by the Minister in respect of the importing, sale, or manufacture, as the case may require, of that new drug, and which licence has not been withdrawn in accordance with regulation 69; and

(b) he has paid an initial fee of five thousand dollars in respect of that licence instead of the registration fee imposed pursuant to regulation 40."

The basis of the respondents' case is contained in the evidence of Mrs. E. Grace Allen-Young. Here is how she put the case in her affidavit:

"3. That since the Food and Drugs Regulations does not provide a particular format that Registration or a licence for importation, sale and manufacture of drugs should take, over the years the Ministry of Health has used a letter form as evidence that the Drug has been licenced or Registered.

4. That this letter includes:

(i) The name of the product;
(ii) The manufacturer of the product;
(iii) The date of approval/registration/licence;
(iv) The dosage form and strength;
(v) An assigned number which is unique to that product and which can be quoted as verification that the requirement of licensing has been met;
(vi) The signature of the person authorized to Register/ licence/approve the use of the drug or their designate;
(vii) The name and address of the competent authority; and
(viii) The legal status of the product where it is a prescription drug.

5. That this format has been accepted by both the local and international Health Care and Pharmaceutical Industry as it contains the requisite information

Then she continued thus:

"6. That locally and internationally the terms "licensing", "Registration" and "approval" are used interchangeably to indicate that applicants have met the prescribed specification of the competent Health Authority on product quality, efficiency and safety.

7. That the difference between the Registration and the Licensing of a drug in these Regulations depends solely upon whether one is dealing with a drug which can be classified as a new drug. Furthermore, a new drug, of which Health - Pro Pycnogenol (Anti-oxidant) is categorized, is licensed whilst any drug other than a new drug is registered."

Then turning to the specific breach she states:

"8. That the relevant documents submitted by the applicant constituted an application for the importation, sale and manufacture of the product Health-pro Pycnogenol (Anti-oxidant) not the advertisement of the said product. Furthermore, at the time the said application was made, the Applicants did not submit an Application for approval to advertise the said product.

9. That there is a general prohibition on the advertisement of any drug which purports to treat, prevent or cure any disease disorder or abnormal physical states falling within the ambit of the First Schedule of the Act."

Referring to the requirements stipulated by legislation and regulations she said:

"10. That if a person wishes to advertise a drug for any disease, disorder or abnormal physical states which falls outside the ambit of the First Schedule then approval must be sought from the Minister of Health.

11. That for consideration of approval the script and layout for aural and visual presentation be submitted along with a sample of the product to be advertised. If television advertisements are involved then as part of the approval process, the advertisements must be viewed.

12. That if the advertisement is approved, the stamp of approval is affixed to the script and the applicant is notified of

the approval by way of a letter. The script as approved, may then be used for advertising.

13. That I crave leave of this Honourable Court to mention and refer to paragraph 9 of the Affidavit of Leslie Giscombe and say that the Ministry of Health did not publish the said Article but merely advised the Gleaner Company to withdraw the said advertisement. I exhibit hereto a copy of letter dated March 25, 1997 sent to the Gleaner Company marked "EGA.1" for identification."

Here is letter of March 24, 1997 referred to in paragraph 13:

"The Editor
The Gleaner Co. Ltd
7, North Street
Kingston

Dear Madam

Re: Advertisement "HEALTH-PRO PYCNOGENOL" - Gleaner, March 25, 1997 A3

Kindly cause to be withdrawn with immediate effect the above-mentioned advertisement which is in breach of the Food & Drugs Act 1964 and Food & Drugs Regulations 1974.

As you will be aware "a person shall not advertise any food, drug, cosmetic or device to the general public for the treatment, prevention or cure of any of the diseases, disorders or abnormal physical states mentioned in the First Schedule" (Food & Drugs Act Section 3(1)}. A copy of this schedule is attached. In addition "a person shall not advertise any drug unless he has first been granted approval in writing by the Minister to do so, and such approval has not been withdrawn at the time of publication of the advertisement" (Food & Drugs Regulations 3(2)}

Evidence of approval of such an advertisement must at all times be requested by the representatives of your Company prior to its acceptance for publication.

Please do not hesitate to contact me if there is need for further information.
Yours sincerely,
PHARMACEUTICAL SERVICES DIVISION

F. Grace Allen-Young (Mrs.)
DIRECTOR

In this context Section 2(1) of the Act is relevant. It reads:

> "2.-(1) In this Act-
>
> "advertisement" includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device;

To reiterate Pycnogenol is a new drug as defined by paragraph 64 of The Food and Drug Regulation of 1975 and the appellant was granted a licence pursuant to paragraph 68 of the Regulations which reads:

> "The Minister shall, within one hundred and twenty days after the filing of an application for a licence to import, sell, advertise for sale, or manufacture a new drug -
>
> (a) notify the applicant whether or not his application is satisfactory; and
>
> (b) if so, may grant a licence to the applicant in accordance therewith."

That subsequent to the unauthorised advertisement in the **Gleaner** there was approval granted for specific advertising can be gleaned from the following correspondence. The initial letter of June 26th, 1977, reads:

> "Mr. Fitzgerald Giscombe
> Chairman & Chief Executive Officer
> Health-Pro (Ja.) Ltd
> 2a Molynes Road
> Kingston 10
>
> Dear Mr. Giscombe,
> **Re: Approval of Pcynogenol Advertisement**
>
> Reference is made to your letter of June 4, which was received on June 13, 1997, and the enclosed book entitled 'Pcynogenol the Super "Protector" Nutrient'. I have perused the 108 page document to find the clinical basis of the claims in Table 1.1. References to the New England Medical Journal are sufficiently imprecise to disallow validation.

You are therefore advised to revamp the advertisement to reflect what can be unequivocally substantiated and advertised in accordance with Section 3 of the Food & Drugs Act. (1964).

Please also note that the appearance of any advertisement that has not been approved in the press is an offence under this said Act.

Yours sincerely,
PHARMACEUTICAL SERVICES DIVISION

E. Grace Allen-Young
DIRECTOR

There was a response on the same day which reads:

"The Pharmaceutical Services Division
Ministry of Health
10 Caledonia Avenue
Kingston 5

ATTENTION; MRS. GRACE ALLEN-YOUNG

Dear Mrs. Allen-Young:

With reference to your correspondence dated June 26, 1997, we have revised our advertisement and now submit the attached for your approval.

We hope that this advertisement is in accordance with Section 3 of the Food & Drug Act, and will therefore be eligible for approval.

Your urgent attention to this matter would be greatly appreciated.

Thank you.

Sincerely yours
HEALTH-PRO (JA.) LTD.

Fitzgerald Giscombe
Chairman & Chief Executive Officer

Then the Ministry gave approval thus:

"Health Pro(Jamaica) Ltd.
2a Molynes Road
KINGSTON 10

Dear Sirs:

ATTENTION: Mr. Fitzgerald Giscombe
Chairman & C.E.O.

RE; ADVERTISING SCRIPT FOR APPROVAL.

This is to inform you that the advertising script for the following produce has been approved.

19A 5 HEALTH-PRO PYCNOGENOL

Attached are copies of the script bearing our stamp of approval

Yours sincerly,
PHARMACEUTICAL SERVICES DIVISION

P. Grace Allen-Young (Mrs.)
For and on Behalf of
The Hon. Minister of Health"

Here is the approved advertisement:

'IS THIS THE ANSWER?

IS THIS WHAT WE HAVE BEEN WAITING FOR?

FREE RADICALS CAN CAUSE ILLNESS AND DEATH

SCIENTISTS HAVE DISCOVERED THAT FREE-RADICALS ARE INVOLVED IN A NUMBER OF MEDICAL DISORDERS AS WELL AS ACCELERATED AGING.

HEALTH-PRO PYCNOGENOL DESTROYS FREE RADICALS!

ASK YOUR DOCTOR, PHARMACIST, HEALTH FOOD STORE, OR AUTHORISED DISTRIBUTOR TODAY. "

It is clear that the appellant was not satisfied with the approved advertisement but wished to advertise in its own discretion.

Has a claim been successfully made for the issue of Mandamas?

De Smith; **Judicial Review of Administration Action** second edition defines Mandamas thus:

> "Mandamus lies to secure the performance of a public duty, in the performance of which the applicant has a sufficient legal interest. The applicant must show that he has demanded performance of the duty and that performance has been refused by the authority obliged to discharge it. It is pre-eminently a discretionary remedy, and the court will decline to award it if another legal remedy is equally beneficial, convenient and effective."

In this case the grant of Mandamus depends as Ms. Cheryl Lewis submitted on the provisions of paragraph 4(1) of the Regulations which was made pursuant to Section 3 of the Food and Drugs Act. To reiterate that section reads in part:

> "3.-(1) A person shall not advertise any food, drug, cosmetic or device to the general public for the treatment, prevention or cure of any of the diseases, disorders or abnormal physical states mentioned in the First Schedule.
>
> (2) A person shall not sell any food, drug, cosmetic or device -
>
> (a) that is represented by label; or
>
> (b) that he advertises to the general public,
>
> for the treatment, prevention or cure of any of the diseases, disorders or abnormal physical states mentioned in the First Schedule.

Then the relevant regulation states:

> 4.-(1) A person shall not advertise any drug unless he has first been granted approval in writing by the Minister to do so, and such approval has not been withdrawn at the time of publication of the advertisement."

The gist of the appellant's claim for the issue of mandamus is that once he is granted a licence to import and sell he is free to advertise without let or hindrance. Here is how the claim was put:

> "10)That when the Applicant herein advertised the new drug for sale on March 25, 1997 it did so in accordance with the therapeutic use for which the new drug is imported into Jamaica under the Food and Drugs Act and Regulations. Nevertheless since April 1997 the Minister of Health has objected to and prevented the applicant from continuing to advertise in accordance with its legal entitlement. As a result the applicant is being severely restricted in its business and is suffering damages.
>
> 11) Attached hereto as exhibits is a series of letters which demonstrate how the respondent herein has stifled the applicant's marketing of the new drug, Pycnogenol, by insisting that there must be no mention of the diseases which Pycnogenol is beneficial for, and by demanding that Health-Pro send all its advertisements to the respondents for censoring before publishing them, despite Health Pro's licence to advertise the new drug for sale in accordance with the therapeutic use for which it is imported under the laws of Jamaica."

The Food and Drugs Act and the corresponding Regulations entrust the Ministry of Health with extensive regulatory powers to ensure that the public is protected against false or misleading advertisement for those items of food or drugs mentioned in the Act or regulations. Further the Ministry has been provided with the necessary means to test the qualities of those drugs over which it has control. That it is empowered to censor advertisements is evidenced by the law previously cited in this judgment. The Ministry has restricted the advertisements in the interest of the health and welfare of the public. This is its legal duty.

The Supreme Court has sanctioned restrictions on the advertisement of Pycnogenal and refused the issue of mandamus to compel the Ministry to permit the appellant to advertise in its own discretion. That decision was correct and ought to be affirmed. So the appeal is dismissed. Consequently the order below is affirmed. Mandamus is refused and the respondent must have its taxed or agreed costs.

PATTERSON, J.A.

I have read the judgments of Downer, J.A. and Langrin J.A. and I agree with their conclusion and the order proposed.

LANGRIN, J.A.

This is an appeal by Health-Pro Jamaica Ltd., a Marketing Company registered in Jamaica, against the refusal of an Order of Mandamus by the Full Court of the Supreme Court (Ellis , Panton , and Granville JJ,) on the 10th July, 1998.

The Motion before the Supreme Court also sought general and exemplary damages but these remedies were not pursued when the matter came up before this Court.

The grounds upon which the relief was sought are stated as under:

> "(1) That the Applicant applied to the Minister of Health for a licence to import, sell and advertise for sale a new drug named Health-Pro Pycnogenol and that instead of issuing a licence in compliance with the Food and Drugs Regulations, 1975, made under the Food and Drugs Act, the Minister issued to the Applicant a letter informing that the drug has been registered under the Food and Drugs Act.
>
> (2) That the grant of registration is inferior to the issue of a licence, and furthermore is not in compliance with the requirements of the said Act and Regulations for treatment of a new drug.
>
> (3) That a grant of registration for a new drug rather than issue of a licence after the licensing fee has been paid, is contrary to regulation 65(1) of the Food and Drugs Regulations 1975.
>
> (4) That the Minister has failed and or refused to grant the proper and appropriate licence to the Applicant after a demand for such has been made by the applicant."

The Chief Executive Officer for Health-Pro International, a company incorporated in the United States of America with registered office in Brooklyn, New York, USA made an application on behalf of Health-Pro International to the Minister of

Health. The application was made in December 1995 through the Pharmaceutical Services Division of the Ministry of Health for a licence to import, sell, and advertise for sale a new drug named Health-Pro Pycnogenol (Antioxidant). He submitted all the relevant documents and drug samples required for completion of the application and paid a fee of Five Thousand Dollars .

By a letter dated March 22, 1996, from the Minister of Health the applicant was informed that the new drug Health-Pro Pycnogenol with the corresponding registration numbers recorded in the letter has been registered under the Food and Drugs Act 1964 as of March 18, 1996. The letter also stated that the "formulations submitted in support of the application has been placed on our records".

It is significant to note that documents submitted with the application for the licence include, United States Patent, statement of information about the manufacturer, statement by the manufacturer on quality control, Certificate of free sale - that the drug is sold without restrictions throughout the United States of America and statement that the manufacturer operates under the jurisdiction of the United States Food and Drug Administration.

In March, 1997, Health-Pro Jamaica Ltd. was registered in Jamaica as a limited liability company for the purpose inter alia of marketing health products and acquired and assumed the business of marketing Health-Pro Pycnogenol in Jamaica. Since March, 1997, Health- Pro Jamaica Ltd. has been importing, selling and advertising for sale the new drug Health-Pro Pycnogenol, Anti-oxidant.

On April 2, 1997 an article was published in the Daily Gleaner stating that the Ministry of Health complained that Health-Pro Jamaica Ltd. had breached the Food and

Drugs Act and Regulations on two grounds. The article prompted two letters from the applicant's lawyer complaining about the contents of the article.

Essentially, the relevant complaint of the appellant is that licencing and registration are two different authorizations, and that in the case of the Food and Drugs Act and Regulations, the latter is inferior to the former. The appellant further complains that the Minister of Health has treated the licencing of a new drug as a mere registration under the Act which has curtailed the appellant's business operations by forbidding it to advertise the new drug for the uses for which it is imported into Jamaica in accordance with its patent and licence.

Mandamus is a remedy which is used to compel the performance of a public duty by a public authority. Where a public body is found to have exercised power improperly the Court would invoke a remedy such as Mandamus to compel its proper performance.

The question which is now sought to be determined is whether the Ministry of Health acted ultra vires the statute and regulations in preventing the appellant from advertising the new drug in conformity with the licence which was granted.

Miss Warren, Counsel on behalf of the appellant contended that once a licence is granted under Regulation 65 it enables one to advertise. That being so, the form of response to the application for a licence by the Minister is inappropriate since the Minister has granted registration instead of a licence.

Miss Lewis, submitted on behalf of the respondent that because there is a general prohibition on advertising of a drug which falls within The First Schedule of the Act the Minister is empowered to regulate all advertisements for the sale of drugs.

She further submitted that in the absence of any form of licence prescribed under the relevant regulation, then the substance of what the appellant received from the Minister should not be interfered with.

Section 3(1) of the Act imposes a prohibition on advertising of a new drug. It states as under:

> "3.-(1) A person shall not advertise any food, drug, cosmetic or device to the general public for the treatment, prevention or cure of any of the diseases, disorders or abnormal physical states mentioned in the First Schedule.
>
> (2) A person shall not sell any food, drug, cosmetic or device -
>
> (a) that is represented by label; or
>
> (b) that he advertises to the general public, for the treatment, prevention or cure of any of the diseases, disorders or abnormal physical states mentioned in the First Schedule."

The Food and Drugs Act has empowered the Minister of Health to make regulations for carrying the purposes and provisions of this Act into effect. The relevant parts of the section are stated as under:

> "**21.** --The Minister may make regulations for carrying the purposes and provisions of this Act into effect and in particular but without prejudice to the generality of the foregoing may make regulations --
>
> (a)...
>
> (b) respecting --
>
> (i) the labelling and packaging and the offering, exposing and advertising for sale of food, drugs, cosmetics and devices;
>
> (ii)...

(iii) the sale, the prohibition of sale or the conditions of sale of any food, drug, cosmetic or device; and

(iv)...

to prevent the consumer or purchaser thereof from being deceived or misled as to its quantity, character, value, composition, merit or safety or to prevent injury to the health of the consumer or purchaser;

(c-e)...

(f) providing for the registration of drugs or devices, the granting of licences for the manufacture or importation of any drug or device and the imposition of fees in respect of any such registration or licence;

(g) exempting any food, drug, cosmetic or device from all or any of the provisions of this Act and prescribing the conditions of such exemption.

Regulation 65 (1) states as under:

"**65.**- (1) A person shall not import, sell, advertise for sale, or manufacture, a new drug unless -

(a) he has been issued a licence by the Minister in respect of the importing, sale, or manufacture, as the case may require, of that new drug, and which licence has not been withdrawn in accordance with regulation 69; and

(b) he has paid an initial fee of five thousand dollars in respect of that licence instead of the registration fee imposed pursuant to Regulation 40.

(2) Any person desirous of obtaining a licence in accordance with paragraph (1) shall make an application to the Minister containing -..."(emphasis supplied).

This does not mean, however, that the drug for which the licence is obtained must not be registered.

Regulation 40 pertains to the registration of the drug for which a licence is obtained under Regulation 65. Regulation 40 provides:

> "**40.** - (1) A person shall not sell, manufacture, import or distribute a drug unless -
>
> (a) that drug has been registered with the Ministry of Health; and
>
> (b) a fee of $25.00 has been paid in respect of such registration.
>
> (2) The Minister may, in his discretion, exempt any person or any drug from the requirements of paragraph (1).

It is important to observe that the Minister is empowered only to issue a licence to import, sell or manufacture a new drug. However, once a person obtains a licence in respect of a new drug which is defined at regulation 64 he may advertise this drug if approval is obtained.

The First Schedule of the Act sets out thirty-three such diseases, disorders or abnormal physical states which include cancers, cataract, diabetes and influenza for which advertising is prohibited.

Regulation 3 (1) states:

> "**3.** --(1) A person shall not advertise any food, drug, cosmetic or device unless such advertisement complies with the requirements of the Act and these Regulations.
>
> (2) Unless specifically required to do so by any enactment, no label or advertisement shall either directly or indirectly make reference to the Ministry of Health and Environmental Control or these Regulations.

Regulation 4(1) makes provision for the grant of approval to advertise and states specifically as follows:

> "**4**.-(1) A person shall not advertise any drug unless he has first been granted approval in writing by the Minister to do so, and such approval has not been withdrawn at the time of publication of the advertisement."

In construing the power exercised by the Minister in granting the licence regard must be given to the expressed prohibition to advertising of a drug for the treatment, prevention or cure of certain ailments as well as the clear and unambiguous provision for the grant of approval to advertise. The contrary argument advanced by the appellant cannot be supported either in principle or as a matter of construction.

It follows logically that if a person wishes to advertise a drug for any disease, disorder or abnormal physical state which falls within the ambit of the First Schedule then approval must be sought from the Minister of Health.

The Minister in my judgment has correctly responded and notwithstanding the nomenclature which has been used in the licence granted to the appellant it is in keeping with the application for the licence and consistent with the Statute. The licencee has the authority to import and sell the new drug Pycnogenol.

I am in full agreement with the Full Court in a judgment written by Panton, J. that the Minister has granted the appellant a licence to import and to sell new drugs, but not to advertise and that the Minister acted in accordance with the provisions of the Statute and fulfilled his statutory duty.

Accordingly, for the reasons stated the appeal is dismissed with costs to the respondent to be agreed or taxed.