REPUBLIC OF TRINIDAD AND TOBAGO

IN THE HIGH COURT OF JUSTICE

CV2011-01394

IN THE MATTER OF THE JUDICIAL REVIEW ACT, CHAP. 7:08

AND

IN THE MATTER OF THE APPLICATION BY VITAMIN AND HERBAL CABINET LIMITED FOR LEAVE TO APPLY FOR JUDICIAL REVIEW OF:

(1) THE DECISION OF THE CHIEF CHEMIST/DIRECTOR OF FOOD AND DRUG IN LATER NOVEMBER, 2010 TO DENY THE APPLICANT'S APPLICATION TO IMPORT FOOD SUPPLEMENTS FROM NATURE'S BOUNTY INC., USA INTO THE MARKET OF TRINIDAD & TOBAGO WHEN IN FACT THE SAID FOOD SUPPLEMENTS WERE PREVIOUSLY PERMITTED TO BE IMPORTED INTO THE MARKET OF TRINIDAD & TOBAGO BY QUEEN'S PHARMACY.

(2) DECISION OF THE CHIEF CHEMIST/DIRECTOR OF FOOD AND DRUG MADE NOVEMBER, 2010 TO STIPULATE THAT IN ORDER TO IMPORT FOOD SUPPLEMENTS THE SAID FOOD SUPPLEMENTS MUST SATISFY THE CRITERIA SET FOR THE IMPORTATION OF PHARMACEUTICALS.

(3) THE DECISION OF THE CHIEF CHEMIST/DIRECTOR OF FOOD AND DRUG MADE SOMETIMES IN 2010 TO RECLASSIFY FOOD SUPPLEMENTS – SPECIFICALLY FOOD SUPPLEMENTS FROM NATURE'S BOUNTY AS "DRUGS" AND IN SO DOING UNFAIRLY CHANGE THE CRITERIA SET FOR THE IMPORTATION OF FOOD SUPPLEMENTS TO THAT SET FOR PHARMACEUTICALS AND IN THE PROCESS ADVERSELY AFFECT THE APPLICANT'S OPPORTUNITY TO IMPORT THE SAID PRODUCTS.

(4) THE DECISION OF THE CHIEF CHEMIST OF FOOD AND DRUG TO WAIVE THE NEW CRITERIA FOR THE IMPORTATION OF FOOD SUPPLEMENTS IN FAVOUR OF ANTHONY P. SCOTT LTD. AND IN SO DOING DEMONSTRATED BIAS AGAINST THE APPLICANT IN MAINTAINING THE APPLICANT MEET THE NEW CRITERIA SET FOR PHARMACEUTICALS.

BETWEEN

VITAMIN AND HERBAL CABINET LIMITED

APPLICANT

AND

THE CHIEF CHEMIST/DIRECTOR OF FOOD AND DRUGS

FIRST RESPONDENT

THE ATTORNEY GENERAL OF TRINIDAD AND TOBAGO

SECOND RESPONDENT

BEFORE THE HON. MADAME JUSTICE JOAN CHARLES

Appearances:

For the Applicant: Mr. K. Wright, instructed by Ms. A. Olowe
For the Respondents: Mr. C. Sieuchand, instructed by Ms. K. Oliverie

Date of Delivery: 31st January, 2012

DECISION

BACKGROUND

[1] The Applicant is a company engaged in the importation and distribution of herbal and nutritional supplements in Trinidad & Tobago. The First Respondent is an agency of the Government responsible for the registration and granting of licenses under the **FOOD AND DRUG ACT, CAP. 30:01** ("the Act").

- THE APPLICATION

[2] By Notice of Application filed on the 13th April, 2011, the Applicant sought the following reliefs:

i. A Declaration that the oral decision made on or around the 30th November, 2010, by the Chief Chemist/Director Food and Drug (CC/DFD), denying it an appointment for registration of Food Supplements from Nature's Bounty unless it complied with the criteria for the importation of pharmaceuticals when in fact the Food and Drug Division previously granted Queen's Pharmacy permission to import the said food supplements from Nature's Bounty without need to satisfy the criteria for pharmaceuticals, amounted to a deprivation of legitimate expectation and is accordingly illegal, null and void and of no effect;

ii. A Declaration that the oral decision by the CC/DFD in March, 2010 to reclassify the food supplements from Nature's Bounty as 'drugs' is unreasonable, irrational and is accordingly illegal, null and void and of no effect;

iii. A Declaration that the oral decision made on or around the 30th June, 2010 by the CC/DFD demanding that it satisfies the criteria established for the importation of pharmaceuticals for its application to import food supplements from Nature's Bounty is unreasonable, irrational and is accordingly illegal, null and void and of no effect;

iv. A Declaration that the decision made sometime between February, 2010 and November 2010 by the CC/DFD to waive the criteria for the importation of food supplements from GNC a subsidiary company of Nature's Bounty, by Anthony P. Scott Limited, and the said Food and Drug Division's oral decision in or around 30th November, 2010 to deny the Applicant the same waiver import/register food supplements from Nature's Bounty Inc., USA – parent company of GNC – is biased, unreasonable, irregular or in an improper exercise of its discretion and accordingly is illegal, null and void and of no effect.

[3] The Grounds upon which the reliefs are being sought are as follows:

i. Queen's Pharmacy was the appointed distributor for food supplements from Nature's Bounty and Disney's Kids' Multi-Vitamins in Trinidad & Tobago. In or around February 2009, the Applicant was told by Nature's Bounty Regional Representative that the distributorship was withdrawn from Queen's Pharmacy and was available. The Applicant thereafter accepted the distributorship for the said food supplements and applied to the CC/DFD to register them but was denied registration.

ii. In March, 2010, the First Respondent orally told the Applicant that it reclassified the food supplements from Nature's Bounty and Disney's Kids' Multi-vitamin as "drugs" thus attributing to the said food supplements the criteria set by the **FOOD AND DRUG ACT** for the registration of pharmaceuticals. This classification was not attributed to the said supplements under the distributorship of Queen's Pharmacy. Furthermore, re-classifying the food supplement as "drugs" rendered it impossible for the Applicant to obtain data which cannot be obtained from the manufacturer – Nature's Bounty. The list of food supplements Queen's Pharmacy was allowed to import replicates the majority of the extended list of food supplements submitted by the Applicant to the CC/DFD for registration and importation.

iii. Subsequent to the denial of registration, the Applicant discovered that the First Respondent – sometime between 1st February, 2010 to 30th November, 2010 – granted a major business entity, Anthony P. Scott Limited, permission to import and register similar food supplements from a subsidiary company of Nature's Bounty – GNC – without the requirement to satisfy the criteria for "drug" classification imposed on the Claimant.

iv. In October, 2010, the Applicant orally complained to the First Respondent about the preferential treatment in favour of others, particularly Anthony P. Scott Limited' that he was treated with bias, unfairness and unreasonableness to which the First Respondent replied that the Food and Drug could sometimes give concession to specific companies under certain conditions.

v. The First Respondent provided inconsistent, arbitrary and conflicting requirements to the Applicant to fulfil the criteria designed for the importation of herbs and supplements under the Herbal Sub-committee of the Ministry of Health. It was further explained that the said committee would exercise its "discretion" to rectify any ambiguity under the **FOOD AND DRUG ACT**.

vi. Sometime between the 1st and 3rd January, 2010, the First Respondent orally told the Applicant that the compulsory requirements to provide a gram each of the active ingredients of each product to be imported was waived.

vii. Between the 1st and 3rd March, 2010, the First Respondent examined labels for specific products and deemed them acceptable for the Trinidad & Tobago market.

viii. Between the 1st and 30th April, 2010, the First Respondent orally told the Applicant to bring documentation for five (5) of the food supplements for examination so that any challenges could be addressed before the next submission window.

ix. On the 29th September, 2010, the First Respondent told the Applicant that he along with others must now submit 'clinical trials' for each product, as the Food and Drug Division was now enforcing strict drug criteria.

x. On the 21st October, 2010, the First Respondent vacated its demands for clinical trials from the Applicant and instead demanded compliance of several other criteria inclusive of:

    a. Compulsory provision of one (1) gram of each active ingredient in each of the food supplement to be imported;
    b. Labels with claims must have support in clinical studies;

c. Proof that laboratory tests confirmed that their products were performing what was known by scientific knowledge;
d. Pharmaceutical documentation;
e. Manufacturing details including a written composition of Nature's Bounty Inc.'s manufacturing procedure for each supplement.

The First Respondent stated that the foregoing would enable it to guarantee the safety of Nature's Bounty's formulae.

xi. On the 19th November, 2010, the First Respondent instructed the Applicant to fax/email a list of the ingredients in the fifty (50) products to determine if the laboratory has them with the possibility of waiving the one (1) gram requirement.

[4] The Applicant contended that the foregoing constituted conflicting, uncertain, unreasonable, irregular and/or improper exercise of the First Respondent's discretion. Consequently, the decisions made by the First Respondent deprived the Applicant of its legitimate expectation. Additionally, the First Respondent acted improperly in its exercise of its discretion and displayed an unreasonable and irrational abuse of power

[5] The Applicant is also seeking an extension of time to make its Application which is outside the period of three (3) months permitted by the **JUDICIAL REVIEW ACT, CHAP. 7:08** and **PART 56.5** of the **CIVIL PROCEEDINGS RULES 1998** (CPR). The grounds for this extension are that:

i. The Applicant was unaware of a time limit to bring an action for Judicial Review. At the end of November, 2010, its Managing Director was told by the First Respondent to supply information relative to fifty (50) products in order for the latter to determine whether its laboratory had data on the said products. The Applicant complied but never received a response although diligent enquiries were made. In the intervening days, the opportunity was lost to register his products with the First Respondent.

ii. The Applicant was also of the opinion that pursuant to the said request for information, negotiations with the First Respondent were continuing.

iii. The Applicant sent a Pre-Action letter[1], dated the 28th January, 2011, giving the First Respondent twenty-one (21) days in which to respond.

ISSUES

[6] There are two main issues to be determined by the Court, namely:

i. Whether the Applicant should be granted leave for Judicial Review although its application was not made within the three (3) months time frame as prescribed by the **JUDICIAL REVIEW ACT**;

ii. Whether the Second Respondent, the Attorney General of Trinidad & Tobago, is an appropriate party to these proceedings.

[1] This letter was not disclosed to the Court. The Respondents did not deny receiving same.

ANALYSIS

Whether the Applicant should be granted leave for Judicial Review although its application was not made within the three (3) months time frame as prescribed by the JUDICIAL REVIEW ACT

- **LEAVE**

[7] The purpose of an applicant seeking Leave of the court to challenge the legality of a public authority's decision is:

i. To safeguard public authorities by deterring or eliminating ill-founded claims without the need for a full hearing of the matter;
ii. To provide a mechanism for the efficient management of the ever growing judicial review caseload, as a large number of cases may be disposed of at this stage with the minimum use of the court's limited resources; and,
iii. To enable an applicant to expeditiously and cheaply obtain the views of the High Court on the merits of his application.[2]

[8] The test to be applied by the Court on an application for Leave for Judicial Review is whether there is an arguable ground for review which has a realistic prospect of success.[3] In **Sharma v Brown-Antoine & Other**[4], Lord Bingham of Cornwall opined:

[2] De Smith's Judicial Review, 6th Edition, p. 839, para. 16-045
[3] Radio Vision Limited v Magistrate Marcia Murray, CV2009-4627
[4] [2007] 1 W.L.R. 780, 787E-H

> *"The ordinary rule now is that the court will refuse leave to claim judicial review unless satisfied that there is an arguable ground for judicial review having a realistic prospect of success and not subject to a discretionary bar such as delay or an alternative remedy … But arguability cannot be judged without reference to the nature and gravity of the issue to be argued. It is a test which is flexible in its application...*
>
> *It is not enough that a case is potentially arguable: an Intended Claimant cannot plead potential arguability to 'justify the grant of leave to issue proceedings upon a speculative basis which it is hoped the interlocutory processes of the court may strengthen': Matalulu v Director of Public Prosecutions [2003] 4 LRC 712 at 733."*

- **DELAY**

[9] In the instant case, the issue of delay in bringing the Application was a live one, as the Respondents argued that this was a bar to Leave being granted to the Applicant. **SECTION 11** of the **JUDICIAL REVIEW ACT** addresses the question of delay and provides:

> *"(1) An application for judicial review shall be made promptly and in any event within three months from the date when grounds for the application first arose unless the Court considers that there is a good reason for extending the period within which the application shall be made.*
>
> *(2) The Court may refuse to grant leave to apply for judicial review if it considers that there has been undue delay in making the application, and that the grant of relief would cause substantial hardship to, or substantially*

prejudice the rights of any person, or would be detrimental to good administration.

(3) In forming an opinion for the purpose of this section, the Court shall have regard to the time when the applicant became aware of the making of the decision, and may have regard to such other matters as it considered relevant."

[10] **PART 56.5** of the **CIVIL PROCEEDINGS RULES 1998** also addresses delay in making an Application for Leave and provides:

"*(1) The judge may refuse leave or grant relief in any case in which he considers that there has been unreasonable delay before making the application…*

(3) When considering whether to refuse leave or grant relief because of delay the judge must consider whether the granting of leave or relief would likely to –

(a) cause substantial hardship to or substantially prejudice the rights of any person; or

(b) be detrimental to good administration."

[11] There is no dispute between the parties that this Application was made out of time. The Respondents submitted that date on which the grounds of the action first arose was the 30th November, 2010. This date was not challenged by the Applicant and the Court accordingly accepts it as the date from which time began to run.

[12] Therefore, the date on which this Application should have been filed expired on the 30th February, 2011. The Applicant is consequently two (2) months late in making its Application, having filed on the 13th April, 2011.

[13] The question which the Court must now address is whether there are good reasons to support an extension of the time within which leave can be sought. In **Abzal Mohammed v Police Service Commission**[5], Kangaloo JA opined that what amounts to a 'good reason' will depend on the circumstances of each case and identified the following as some of the factors which may be taken into account:

i. Length of the delay;
ii. Reason for the delay;
iii. Prospect of success;
iv. Degree of prejudice;
v. Overriding objective that justice is to be done; and,
vi. Importance of the issues involved in the challenge.

Further, in **R v Secretary of State for Trade and Industry *ex. p.* Greenpeace**[6], Maurice Kay J. opined that the following questions are to be asked when concluding if the reasons given are sufficient to extend the time:

"(i) Is there a reasonable, objective excuse for applying late?

[5] C.A. Civ. 53/2009
[6] [1999] All E.R. 1232

(ii) What, if any, is the damage, in terms of hardship or prejudice to third party rights and detriment to good administration, which would be occasioned if permission were now granted?

(iii) In any event, does the public interest require that the application should be permitted?"

[14] The reasons given by the Applicant as to why the Application was made two (2) months out of time is contained in Paragraph 5 of its Statement in Support of the Application, as follows:

i. At the end of November, 2010, the First Respondent requested the Applicant to supply information regarding fifty (50) products in order for the First Respondent to determine whether its laboratory had data on the said product.

ii. The Applicant complied and while awaiting a reply from the First Respondent lost the opportunity to file for leave for Judicial Review and also the opportunity to register its product.

iii. In addition, the Applicant was of the view that pursuant to the request to supply the information to the First Respondent negotiation between the parties were still ongoing. However, no response was ever received by the Applicant.

iv. Further, a Pre-action Letter, dated the 28th January, 2011, was sent to the First Respondent which gave the latter twenty-one (21) days to respond.

[15] In support of its contentions, the Applicant cited the case of **R v London Borough of Harrow *ex p.* Carter**[7], where the court held that it would be premature to commence Judicial Review Proceedings where the possibility of a resolution between the parties "remained alive". The Applicant submitted that the possibility of resolution remained alive until the latest efforts were made to contact and hear from the First Respondent as to whether there was information in its laboratory regarding the fifty (50) products identified for importation.

[16] The Respondents have contended that these reasons do not disclose sufficient grounds for the extension to be granted and is in breach of **PART 56.3(3)** of the **CPR** which provides:

> *"The application must state –*
>
> *… (g) whether any time limit for making the application has been exceeded and, if so, why …"*

[17] In support of their contention, the Respondents cited the cases of **Jones v Solomon**[8], **Digicel Trinidad and Tobago Limited v Macmillian & Others**[9] and **R v Secretary of State for Trade and Industry, *ex. p.* Greenpeace Ltd.**[10]. These cases supported the view that the requirement to move promptly is part of the strict discipline of Judicial Review proceedings and that the three (3) month time limit is not an entitlement but a maximum which should rarely be exceeded.

[7] (1994) 26 H.L.R. 32
[8] (1989) 41 W.I.R. 299
[9] CV03320-2006, 27-36
[10] [1998] Env. L.R. 418, 425

[18] In addition to the reasons posited for the Applicant's delay in making its Application, the Court had regard to the following aspects of the Affidavit of Anthony Williams, the Managing Director of the Applicant:

i. 2007 - Anthony Williams contacted Nature's Bounty Inc., USA to be their agent in Trinidad & Tobago so as to distribute one of their products, 'Good and Natural'.
ii. 2008 – Anthony Williams received a response from Nature's Bounty that an opportunity had arisen to market products in the Trinidad & Tobago Market.
iii. October 2009 – Initiated registration process with the CC/DFD.
iv. Anthony Williams was in constant oral communication with the CC/DFD until January, 2010.
v. January 2010 – Anthony Williams was told to obtain and return with labels of the products he wished imported so as to determine if they are suitable for the Trinidad & Tobago market.
vi. February 2010 – Payment of $720.00, as requested by the CC/DFD, for examination of labels for twenty-four (24) food supplements intended for importation. Also, Anthony Williams applied for permission to import six (6) samples of each product he wished to bring into the market.
vii. March 2010 – Report on label examination received which reclassified 'food supplements' as "drugs" within the Act. Received approval to import the six (6) samples and same were imported. The CC/DFD gave the Applicant one hundred and twenty (120) days from the importation of said samples to complete all aspects of registration.

viii. April 2010 – Completed registration of said samples. CC/DFD indicated that all submissions were on hold for a quorum for the Herbal Sub-Committee.

ix. September, 2010 – Anthony Williams attended a meeting of the Natural and Alternative Medicine Association of Trinidad and Tobago, where he expressed his dissatisfaction in acquiring registration with the CC/DFD. Also, attended meeting at the CC/DFD expressing his disappointment with the inconsistent application of the criteria for the registration of his products. He was advised to contact the Chairman of the Drug Committee, Mr. Anton Cumberbatch.

x. 30th September, 2010 – Anthony Williams wrote to Mr. Anton Cumberbatch requesting an audience to review the demands for clinical trials of the food supplement. No response has been received to date.

xi. 3rd October, 2010 – Anthony Williams wrote to the Minister of Health requesting an audience to address, what he deemed to be, unfair and biased treatment by the CC/DFD.

xii. 21st October, 2010 – Anthony Williams met with the Head of Department of the CC/DFD, Ms. Alvarez and raised his concerns about preferential treatment in favour of some entities which were not required to comply with criteria the Applicant did.

xiii. November 2010 – Anthony Williams sought approval for the waiver of the compulsory one (1) gram of each ingredient of the food supplement intended to be imported. In response, he was told to fax/email the list of ingredients in the fifty (50) products from Nature's Bounty so that the CC/DFD can determine

whether the ingredients were in their laboratory. The Applicant complied but received no reply to date.

[19] Having regard to the evidence and the guidance from **Abzal Mohammed v Police Service Commission** and **R v Secretary of State for Trade and Industry ex. p. Greenpeace**[11], the Court is satisfied that there was and is good reason for the Applicant's delay in bringing this Application for Leave for Judicial Review. The Applicant through no fault of his own was being shuttled to and fro by the CC/DFD for various reasons. It was during this time of assumed continuous negotiations that the time for filing elapsed. Further, in **R v Commissioner for Local Administration, ex. p. Crydon London Borough Council**[12], Woolf LJ opined that the delay provisions should not be construed technically and strictly against a claimant who has behaved sensibly and reasonably in the circumstances of the case.

[20] In addition, the court in **R v Secretary of State for Foreign and Commonwealth Affairs, ex. p. World Development Movement**[13], held that the general importance of the matter to be reviewed may in itself be a reason for resolving the substantive issues in a case where there has been a delay. On the issue of the importance of this matter, the Court agrees with the Applicant that this Application is of general importance to the public; since the **FOOD AND DRUG ACT** did not contemplate 'food supplements' when setting the criteria for the importation of pharmaceuticals into the Trinidad & Tobago market.

[11] *Op. cit.*
[12] [1989] 1 All E.R. 1033, 1045
[13] [1995] 1 W.L.R. 386, 402

[21] In coming to the conclusion that the time ought to be extended for the Application for Leave for Judicial Review, the Court took guidance from the following cases:

i. **R v Stratford-on-Avon District Council, ex. p. Jackson**[14], leave for Judicial Review was granted notwithstanding a nine (9) month delay. The court held that although Jackson's application had been made late there was a good reason for the delay and the time for filing was accordingly extended.

ii. **Caswell v Dairy Products Quote Tribunal for England and Wales**[15], leave for Judicial Review was granted to the applicant although two (2) years had elapsed.

iii. **Chandresh Sharma v The Honourable Patrick Manning & Others**[16], the application for judicial review was made four (4) years late. The Court of Appeal[17] held that the fact that what was alleged was a 'continuing breach' of a continuing duty and an affront to good administration provided good reason to extend the time for making of the application.

[22] Accordingly, the Court does not consider the two-month delay enough to deny the Applicant leave for Judicial Review in light of the diligent efforts that were being made at the time to have the issues resolved.

[14] [1985] 3 All E.R. 769
[15] [1990] 2 All E.R. 434
[16] Civ. App. No. 144/2005
[17] Upheld by the Privy Council

Whether the Second Proposed Defendant, the Attorney General of Trinidad & Tobago, is an appropriate party to these proceedings

[23] The Applicant contended that the Second Respondent ought to be a party to these proceedings based on **SECTION 19** of the **STATE LIABILITY AND PROCEEDINGS ACT, CHAP. 8:02** which provides:

> *"Subject to this Act and to any other written law proceedings against the state shall be instituted against the Attorney General."*

[24] Further, the Applicant contended that the Attorney General[18] is a servant[19] of the state within the definitions given by **SECTION 2** of the **STATE LIABILITY AND PROCEEDINGS ACT** and therefore the legal representative of the First Respondent.

[25] The Respondents submitted that the very nature of Judicial Review is that it must be brought against the person(s) or authority(ies) responsible for making the decision that is under review. Therefore, the Application does not disclose any challenge to any decision made by or on behalf of the Second Respondent. Accordingly, the Second Respondent ought to be

[18] Section 2(3): Any reference in Parts III [Judgments and Executions] or IV [Miscellaneous and Supplemental] to civil proceedings by or against the State, or to civil proceedings to which the State is a party, shall be construed as including a reference to civil proceedings to which the Attorney General is a party; but the State shall not for the purposes of Parts III and IV be deemed to be party to any proceedings by reason only that they brought by the Attorney General upon a relation of some other person.

[19] Section 2(2): "servant", in relation to the State includes an officer who is a member of the public service and any servant of the State, and accordingly … includes –

(a) a Ministry of the State …

(f) any officer, employee or servant of a statutory corporation.

struck out as a party to these proceedings pursuant to **PART 19**[20] of the **CPR**.

[26] In **Marilin Sammy-Wallace v Attorney General**[21], Jamadar J. (as he then was) held that the Attorney General was not a relevant party in Judicial Review proceedings where he/she is not directly affected.

[27] The Court is of the view that the outcome of this matter would directly affect the State as the substantive issues to be ventilated affect the interpretation of the **FOOD AND DRUG ACT** and whether its provisions would apply to the importation of food supplements into the Trinidad & Tobago market. Accordingly, the Second Respondent is a proper party to these proceedings.

CONCLUSION

[28] In the circumstances, I order:

i. Leave for Judicial Review is granted;
ii. The Attorney-General is a proper party to these proceedings;
iii. The Respondents to pay the Applicant's costs in the application, to be assessed in default of agreement.

JOAN CHARLES
JUDGE

[20] Addition and Substitution of Parties
[21] H.C.A. S-623/2003