IN THE COURT OF APPEAL OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

In the matter of an Application for Mandamus in the nature of Writs of Certiorari, Mandamus and Prohibition under and in terms of Article 140 of the Constitution of the Democratic Socialist Republic of Sri Lanka

CA (Writ) Application No. 164/2016

Manoj Roshan Wewage,
No. 70/4 B, 4th Lane,
Moragasmulla, Rajagiriya.

Petitioner

Vs.

1. National Medicines Regulatory Authority,
   No. 120, Norris Canal Road,
   Colombo 10.

2. Director General of Health Services,
   Ex-officio Member,
   National Medicines Regulatory Authority,
   Ministry of Healthcare & Nutrition,
   "Suwasiripaya",
   No. 385, Rev. Baddegama Wimalawansa
   Thero Mawatha, Colombo 10.

3. Director, Medical Technology &
   Supplies,
   National Medicines Regulatory Authority,
   No. 120, Norris Canal Road,
   Colombo 10.

4. The Chairman,
   Appointed Member,
   National Medicines Regulatory Authority,
   No. 120, Norris Canal Road, Colombo 10.

5. Jenburkt Pharmaceuticals Limited,
   No. 93, J.P. Road, Andheri (West),
   Mumbai – 400 058, India.

6. Hon. Rajitha Senaratne,
   Minister of Health, Nutrition &
   Indigenous Medicine,
   Ministry of Health, Nutrition and
   Indigenous Medicine,
   No. 385, Rev. Baddegama Wimalawansa
   Thero Mawatha, Colombo 10.

7. Hon. Attorney General,
   Attorney General's Department,
   Colombo 12.

Respondents

Before: **P. Padman Surasena, J / President of the Court of Appeal**
Arjuna Obeyesekere, J

Counsel: Panduka Abeynayake with S. Kalalpitiya for the Petitioners

Suranga Wimalasena, Senior State Counsel for the 1st – 4th Respondents

Riad Ameen with Rushitha Rodrigo for the 5th Respondent

Written Submissions of the 5th Respondent tendered on: 10th September 2018

Decided on: 05th October 2018

Arjuna Obeyesekere, J

When this matter was taken up for argument on 11th July 2018, learned Counsel for all parties moved that this Court pronounce judgment on the written submissions that the parties would tender. However, this Court observes that written submissions have not been tendered on behalf of the Petitioner.

The Petitioner has filed this application seeking *inter alia* the following relief:

(a) A Writ of Certiorari to quash the decision of the 1st - 4th Respondents to register 'Powergesic Gel', which is an anti-inflammatory drug used to treat pain;

(b) A Writ of Certiorari to quash the decision of the 1st - 4th Respondents to register the 5th Respondent as a supplier of Pharmaceuticals products to Sri Lanka;

(c) A Writ of Mandamus compelling the 1st - 4th Respondents to cancel the registration issued in respect of 'Powergesic Gel'.

The facts of this application very briefly are as follows.

The Petitioner states that he is a businessman involved in the building and construction industry. He claims that he has instituted this application on his own behalf and in the Public Interest to "prevent grave detriment being caused to Social Security & Welfare of the people or the citizens of the Democratic Socialist Republic of Sri Lanka."

The Petitioner claims that he is a regular user of 'Powergesic gel' and that on or about 15th February 2016, he purchased a tube of 'Powergesic Gel' from a pharmacy.[1] The Petitioner claims that upon application of the said gel, he developed an unbearable irritation and burning sensation. The Petitioner claims to have seen a doctor and states that his doctor had identified the presence of the substance 'Methyl Salicylic acid', a compound not mentioned in the list of ingredients in the said gel, to be the cause of the alleged allergic reaction. The Petitioner has not annexed any proof to establish how this un-named doctor came to such a conclusion nor has the Petitioner annexed any supporting material from this doctor.

[1] In proof of such purchase, the Petitioner has annexed a hand written receipt, marked 'P6', the authenticity of which has been disputed by the 5th Respondent.

The said gel has been manufactured in India by the 5th Respondent and the registration[2] to import the said gel to Sri Lanka issued by the 1st Respondent, the National Medicines Regulatory Authority[3] was held during this period by a company which we shall refer to as 'AAA', for the reason that the said company is not a party to this application. By letter dated 17th February 2016, annexed to the petition marked **'P7'**, the Petitioner complained to 'AAA' about the aforementioned incident.

The Petitioner states that 'AAA' had referred samples of 'Powergesic Gel' to an analytical laboratory, which confirmed the presence of 'Methyl Salicylate' in the sample produced to the said laboratory. Although a copy of the test report has been annexed to the petition, marked as **'P8(f)'**[4], the Petitioner has not disclosed to this Court as to how he obtained a copy of the said report.

The Petitioner claims that 'Methyl Salicylic Acid' has multiple adverse side effects but has failed to submit any credible proof in support of this claim. This position of the Petitioner has been denied by the 1st Respondent, who has taken up the position that 'Methyl Salicylate' is a common ingredient in many analgesic balms and that there is no truth to the claim of the Petitioner

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[2] The Certificate of Registration issued by the 1st Respondent National Medicines Regulatory Authority has been annexed to the petition, marked 'P5'.

[3] The National Medicines Regulatory Authority has been established in terms of the National Medicines Regulatory Authority Act No. 5 of 2015. It functions *inter alia* as the central regulator for all matters connected with the registration and licensing of medicines. Section 58 (1) thereof specifies that, "no person shall manufacture or import any medicine without registering such medicine with the Authority and obtaining a license from the Authority therefor".

[4] The test report 'P8(f)' does not disclose the presence of 'Methyl Salicylic acid' as claimed by the Petitioner but only the presence of 'Methyl Salicylate', which, according to the 5th Respondent are two different compounds.

that the said ingredient causes adverse effects. The Petitioner claims further that the presence of 'Methyl Salicylic acid' in the said gel has not been declared by the manufacturer, either on the packaging or in the data submitted by 'AAA' at the time it sought the Certificate of Registration in respect thereof, from the 1st Respondent.

The Petitioner states that the 1st Respondent has a statutory duty in terms of the National Medicines Regulatory Authority Act No. 5 of 2015 to ensure the availability of safe and efficacious drugs and that if any drug is unsafe for human use, the registration should be cancelled. The Petitioner has claimed that the said gel is unsafe for human use as it contains 'Methyl Salicylic acid'. It is on this basis that the Petitioner is seeking a Writ of Certiorari to quash the registration issued in respect of the said gel as well as to quash the registration of the 5th Respondent as a supplier of pharmaceutical products to Sri Lanka.

It appears from the statement of objections of the 1st Respondent that the 1st Respondent was not aware of this incident until the filing of this application. The Petitioner has not produced any documents to establish that he had brought this incident to the attention of the 1st Respondent nor has the Petitioner explained why he has not, at the least, informed the 1st Respondent of this incident. The 1st Respondent has taken up the position that 'AAA', being the holder of the Certificate of Registration during the time the purported incident occurred, was under a duty to notify the 1st Respondent of any information received which cast doubt on the continued validity of the data that has been submitted by 'AAA' itself in connection with the

application for the Certificate of Registration[5] but that 'AAA' has not complained to the 1st Respondent.

The National Medicines Regulatory Authority Act contains stringent standards that an applicant seeking the registration of a drug must meet and detailed provisions with regard to the steps that should be taken by the 1st Respondent prior to the registration of a drug.[6] The Petitioner has not produced any material to establish that the registration by the 1st Respondent of the said gel, as evidenced by '**P5**', has been irregular or that the said registration should be cancelled. In the absence of any evidence of wrongdoing by the 1st Respondent, this Court does not see any merit in this application nor any legal basis to issue the Writs of Certiorari and Mandamus prayed for.

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[5] Regulation 8 (b) of the Regulations made by the Minister of Health, under Section 38 of the Cosmetics, Devises and Drugs Act, No. 27 of 1980 as amended and published in Extraordinary Gazette Notification No. 378/3 dated 02nd December 1985, produced by the 1st Respondent, marked "R1", reads as follows: "The holder of a Certificate of Registration of a drug shall forthwith inform or notify the Authority of any information received by him that casts doubt on the continued validity of the data which was submitted with, or in connection with the application for the registration of the drug, for the purpose of assessing the safety, quality or efficacy of the drug."

[6] Section 59 of the National Medicines Regulatory Authority Act, No. 5 of 2015 reads *inter alia* as follows:

(1) Any person who intends to manufacture or import any medicine shall make an application for the registration of that medicine in the prescribed form to the Authority.
(2) The application shall be accompanied by the prescribed particulars, the samples of the medicine and the prescribed fee.
(4) The Authority shall upon receipt of an application submit that application together with the sample of the medicine and all particulars, available-

(a) to the Medicines Evaluation Committee, for the revaluation of the application and the medicine considering the need to ensure the availability of efficacious, safe and good quality medicine relevant to the healthcare needs of the public at an affordable price; and
(b) to the National Medicines Quality Assurance Laboratory, for testing of the quality of the medicine.

This Court is of the view that a reasonable person claiming to act in the public interest would have complained to the 1st Respondent of any sub-standard drug in the market. The conduct of the Petitioner and 'AAA' in not reporting this incident to the 1st Respondent gives rise to suspicion whether this application has been filed with an ulterior motive. It is in this context that this Court would like to examine the arguments raised in the written submissions filed on behalf of the 5th Respondent, namely that the Petitioner has deliberately withheld material facts from this Court and misrepresented to this Court material facts and thereby abused the due process of this Court by filing this application.

The 5th Respondent, who is a manufacturer of pharmaceutical products in India and which is listed on the Bombay Stock Exchange, has stated that 'AAA' was appointed as the distributor of all its products in Sri Lanka in August 2008 for a period of 10 years. Due to various issues that had arisen between the 5th Respondent and 'AAA', the 5th Respondent had terminated the Distributorship with 'AAA' with effect from 1st March 2016, as evidenced by letter dated 25th November 2015 produced by the 5th Respondent marked '**5R3**'. Thus, at the time of the alleged incident (i.e. 15th February 2016), the relationship between the 5th Respondent and 'AAA' was strained. It is in this factual background that the 5th Respondent claims that this application has been instigated by 'AAA' as a result of the termination of their business relationship and that this is a collusive action between the Petitioner and 'AAA'.

In order to prove this position, the 5th Respondent has submitted that the Petitioner is the Managing Director of a company named, 'MN Homes Developers (Pvt) Limited' which is engaged in the construction business and

that according to the website of this company, it has undertaken several construction projects for 'AAA', the Managing Director of 'AAA' and for related companies of 'AAA'. This is borne out by the documents produced by the Petitioner marked '**5R10**', which the 5th Respondent states has been downloaded from the website of the said company. This Court observes that apart from a bare denial, the Petitioner has not said anything in his counter affidavit in this regard. The Petitioner has not disclosed to this Court that he has a relationship with 'AAA', either personal or business. In fact, as set out earlier, the Petitioner has claimed that he is filing this application not only for himself but also in the public interest. This Court is of the view that the existence of this relationship should have been disclosed to this Court by the Petitioner, as it is material and has a direct bearing on the facts of this application and the relief claimed by the Petitioner.

Our Courts have consistently held that a party invoking the Writ jurisdiction of this Court must come with clean hands and utmost good faith. The Supreme Court in **Liyanage & another v Ratnasiri, Divisional Secretary, Gampaha & Others**[7] citing the case of **Jayasinghe v National Institute of Fisheries and Nautical Engineering and Others**[8] has held as follows:

> "The conduct of the Petitioner in withholding these material facts from Court shows a lack of *uberrima fides* on the part of the Petitioner. When a litigant makes an application to this Court seeking relief, he enters into a contractual obligation with the Court. This contractual relationship

[7] 2013 (1) Sri LR 6 at page 15.
[8] 2002 (1) Sri LR 277.

requires the Petitioner to disclose all material facts correctly and frankly. This is a duty cast on any litigant seeking relief from Court.

In the case of **Blanca Diamonds (Pvt) Limited v. Wilfred Van Els and Two Others**[9], the Court highlighted this contractual obligation which a party enters into with the Court, requiring the need to disclose *uberrima fides* and disclose all material facts fully and frankly to Court. Any party who misleads Court, misrepresents facts to Court or utters falsehood in Court will not be entitled to obtain redress from Court. It is a well-established proposition of law, since Courts expect a party seeking relief to be frank and open with the Court. This principle has been applied even in an application that has been made to challenge a decision made without jurisdiction. Further, Court will not go into the merits of the case in such situations."

In **Timberlake International Pvt. Ltd. Vs. The Conservator General of Forests**[10], the Supreme Court, having held that the conduct of an applicant seeking Writs of Certiorari and Mandamus is of great relevance because such Writs, being prerogative remedies, are not issued as of right, and are dependent on the discretion of court, stated as follows:

"It is trite law that any person invoking the discretionary jurisdiction of the Court of Appeal for obtaining prerogative relief, has a duty to show *uberrimae fides* or (utmost) good faith, and disclose all material facts to

[9] 1997 (1) Sri LR 360.
[10] S.C. Appeal No: 06/2008 SC Minutes of 2nd March 2010.

this Court to enable it to arrive at a correct adjudication on the issues arising upon this application."

The 5th Respondent has referred to several other matters that have either been suppressed from this Court or misrepresented by the Petitioner. The necessity to go into such matters does not arise as this Court is of the view that the non-disclosure of the relationship between the Petitioner and 'AAA' is sufficient for this Court to uphold the argument of the 5th Respondent that the Petitioner has not come to Court with clean hands. This Court is of the view that the Petitioner has breached its duty by this Court and has deliberately suppressed its relationship with 'AAA' to this Court. It is apparent to this Court that had this relationship been disclosed, this Court would not have issued notices on the Respondents in the first instance. On this basis alone, this Court is of the view that this application is liable to be dismissed.

If the facts disclosed in the petition are examined in the light of the aforementioned material placed before this Court by the 5th Respondent, it becomes apparent that this application is a collusive action between the Petitioner and 'AAA' and has been filed by the Petitioner for a collateral purpose. How else could one explain the failure of the Petitioner or 'AAA' not to refer the alleged incident to the 1st Respondent or the deliberate withholding of the relationship between the Petitioner and 'AAA'? Taking into consideration all of the above, it is evident to this Court that the Petitioner has filed this application for a collateral purpose and has abused the process of Court, on which basis too, this application is liable to be dismissed.

There is one other matter that this Court would like to advert to, which is the analytical report marked '**P8(f)**' submitted by the Petitioner which claims to have found evidence of 'Methyl Salicylate' in the samples submitted by 'AAA'. In the light of the displeasure that existed between 'AAA' and the 5th Respondent during this period, the mere fact of the samples being submitted by 'AAA' for testing is sufficient to raise a doubt with regard to the integrity of the samples that were given for analysis.

The 5th Respondent has categorically stated that 'Methyl Salicylate' is not an ingredient contained in 'Powergesic gel'. According to the 5th Respondent, in accordance with good manufacturing practices, it retains samples of each batch of the gel. After this application was filed, the 5th Respondent had initiated an analytical test of two samples taken from the same batch of the gel as the one tested by 'AAA', at an analytical laboratory in India. According to the test report of the said laboratory in India, submitted by the 5th Respondent marked '**5R15(c)**' and '**5R15(d)**', there is no evidence of 'Methyl Salicylate' in the samples of 'Powergesic gel' forwarded by the 5th Respondent. While this Court cannot come to any conclusions on the contents of the said gel, it appears to this Court that the allegation of the Petitioner that the said gel contains 'Methyl Salicylic Acid' is unfounded

The final matter that this Court needs to decide is whether costs should be ordered, taking into consideration all of the circumstances of this case and the conduct of the Petitioner. In this regard, this Court would be guided by the following observation of the Supreme Court in **Leon Peris Kumarasinghe vs. Samantha Weliveriya:**[11]

[11] S.C. Spl. L.A. No. 37/2012 - SC Minutes of 12th November 2013.

"This Court cannot over emphasize the need to appropriately deal with litigants who attempt to abuse the process of Court and thereby cause unnecessary delay and costs to other parties, in order to ensure that in the future, litigants will not be tempted to indulge in such ill- conceived practices."

In the above circumstances, this Court does not see any merit in this application and accordingly dismisses this application, with costs fixed at Rs. 200,000 payable by the Petitioner to the State.

Judge of the Court of Appeal

P. Padman Surasena, J/ President of the Court of Appeal

I agree.

President of the Court of Appeal