



REPUBLIC OF KENYA
IN THE HIGH COURT OF KENYA

AT MOMBASA

CONSTITUTIONAL PETITION NO.63 OF 2013

1. REVITAL HEALTHCARE (EPZ) LIMITED

2. RAJNIKANT C. VORAPETITIONERS

VERSUS

1. MINISTRY OF HEALTH

2. THE CABINET SECRETARY FOR THE MINISTRY OF HEALTH

3. PUBLIC SERVICE COMMISSION

4. PHARMACY & POISONS BOARD

5. DR. DOMINIC MUTIE

6. ATTORNEY GENERAL RESPONDENTS

JUDGMENT

THE PETITION

1. The Petition before court dated 30th October 2013 seeks orders for:-

- a. **A Declaration that the Petitioners' fundamental rights to fair administrative action and protection of the right to property have been violently transgressed and trampled up by the Respondents.**
- b. **A Declaration that the Petitioners' are entitled to damages for the breach of their fundamental rights and freedom and that this honorable court do determine the appropriate manner of awarding compensation to the Petitioners to compensate for the Petitioners' suffering, losses and damages arising from the Respondents' violations of the Petitioners' fundamental rights and freedoms.**
- c. **A Declaration for exemplary damages.**
- d. **A Declaration that the 4th respondent's GMP Inspection Report of the Petitioner's factory be declared as illegal and unconstitutional thus null and void and an order directed against the 1st, 2nd and 4th Respondents to destroy under oath all copies of the 4th respondent's**

GMP Inspection Report that the 1st, 2nd and 4th Respondents have in their possession.

- e. **An order directed against the 1st, 2nd and 4th Respondents to correct under oath all records that the 1st, 2nd and 4th Respondents have in their possession concerning the 1st Petitioner and its registered trademarked syringes, “Cady”, “Revital”, “ABC”, and “DCK” removing all mention of any of the contents and/or observations of the respondent's “GMP Inspection Report”.**
- f. **An order directed against the 1st, 2nd, 4th and 5th Respondent to supply under oath to the 2nd Petitioner a list of all persons, organizations whatsoever given access to the 4th Respondent's “GMP Inspection Report”.**
- g. **A conservatory order against the distribution, circulation and/or any other use of the 4th respondent's “GMP Inspection Report” and the 5th respondent's memo dated 4th December 2012.**

THE PETITIONERS' CASE

2. The Petition is supported by the affidavit of Rajnikant Chandulal Vora sworn on 30th October 2013, on his own behalf and in his capacity as a shareholder/director with the authority of the board of directors of the First Petitioner. In a nutshell, the First Petitioner company manufactures registered trademarked syringes, “Cady”, “Revital”, “ABC”, and “DCK” which it supplied to the Ministry of Health sometime in the year 2012. The Ministry of Health is said to have complained about the quality of the syringes which, the Petitioners maintains, was a user-challenge and not a manufacturing defect. The Petitioners were later shown an Internal Memo from the Fifth Respondent to the Permanent Secretary in the Ministry of Public Health and Sanitation dated 4th December 2012, and copied to the Ministerial Tender Committee, still raising concerns about the quality of their products. As a result of these complaints, the Pharmacy and Poisons Board sent two representatives to inspect the Petitioners' facility and product on 11th – 12th February 2013.

3. A damning report, **the GMP Inspection Report**, was prepared from the said inspection. The Ministry of Health is accused of having maliciously prompted the World Health Organization (W.H.O.) to suspend the Petitioner's Performance Quality Safety Certification between 15th February and 8th May 2013 by giving them a copy of the inspection report. The suspension was lifted when the devices were revalidated after modification of the devices. During the period of suspension, the Petitioner was not able to sell their product to purchasers that required the PQS Certification – (although the Ministry of Health is not one of them) – thus occasioning them losses. Whether or not related to this Report, the Petitioner's subsequent tender bid to the Ministry of Health was unsuccessful.

THE RESPONDENTS' CASE

4. The Fourth Respondent filed an affidavit in opposition to the Petition, sworn on 30th December 2013 by Dr. Kipkirich Koskei, Chief Pharmacist, Registrar and Secretary to the Pharmacy and Poisons Board (PPB). He stated that the PPB is mandated to control, supervise and manage trade of pharmacy in all aspects. The PPB after consultation with industry stakeholders, the Petitioners included, developed Guidelines on Submission of Documentation for Regulations of Medical Devices which came into operation through Legal Notice No.191 and 192 of 2010. With the authority drawn from the guidelines, the PPB sent representatives to inspect the Petitioners' manufacturing facilities. The Petitioners were very cooperative during the inspection, and did not raise any question as to its legality or jurisdiction at the time. Following the inspection, the PPB impounded all “Cady” syringes and proceeded to prepare an inspection report purely for administrative and internal use. The report was eventually forwarded to W.H.O. as per the request of the international body, which apart from certifying the Petitioner's product, was a stakeholder in the vaccination exercise during which the defect in the syringes had first been reported. He urged the court to dismiss the Petition as being an abuse of court process, and lacking in

proper cause of action against the PPB.

SUBMISSIONS

5. The Petitioners filed written submissions dated 21st July 2013. It was submitted that after complaints were raised, it had taken steps to investigate and reasonably thought the matter concluded as a user-error. The Respondents action of conducting an inspection and thereafter sharing the report with W.H.O. without giving the Petitioners an opportunity to be heard was a breach of the Petitioners Article 47 right to fair administrative action. It was submitted that the Petitioner's product, a syringe, did not fit into the definition and description of items under the control of the PPB as per Sections 2 and 35A of the Pharmacy and Poisons Act [Cap 244 of the Laws of Kenya]. Therefore the Pharmacy & Poisons Board's ("PPB") inspection of the Petitioners' premises and device, including the report are illegal breaches of the Petitioners' rights and freedoms under Article 47 (1) of the Constitution.

6. The Fourth Respondent filed written submissions dated 3rd July 2014. It was submitted that the PPB have the legal mandate to regulate medicinal substances by virtue of Sections 2 and 35C of the Pharmacy and Poisons Act. Section 44 of that Act allows the Minister concerned to consult with the PPB to make rules in respect of medicinal devices. It was against this backdrop that the PPB conducted an inspection on the Petitioner, with the Petitioners' full knowledge and cooperation. The Fifth Respondent concluded that the present allegations in the Petition were therefore an afterthought resulting from the negative outcome of the inspection.

ANALYSIS

7. From the facts, the Petitioners main contentions are that:

- a. The Pharmacy and Poisons Board (PPB) in preparing the GMP Inspection Report ("**Inspection Report**") was acting outside of its mandate. In the Petitioners' opinion, the bodies with the mandate to inspect and evaluate medical devices are the Nursing Council of Kenya (NCK) by virtue of Regulation 3(1) of the Nurses (Nurses Commodities) Regulations 2012 and the Kenya Bureau of Standards (KEBS) which develops, promotes and controls the Kenyan manufacturing standards under sections 7(2)(a), 12(1), 13, 14 and 14A of the Standards Act [Cap 496 of the Laws of Kenya] – both of which were not involved in the said inspection exercise.
- b. The Ministry of Health in sending a damning report to the W.H.O. without giving the Petitioners' an opportunity to defend itself, or without even copying the Petitioners, and especially since the Ministry does not even rely on W.H.O.'s PQS Certification, was malicious and a breach of the Petitioners' right to fair administrative action.
- c. The Public Service Commission has failed to respond on requests by the Petitioner to investigate its complaints against the public officers engaged in the Ministry of Health or otherwise address the Petitioners complaints, thus breaching it's Constitutional mandate to act with integrity.

8. The allegations made by the Petitioners raise factual gaps, and a Constitutional Petition would be an inappropriate forum to embark on filling those gaps. Specifically, it cannot be conclusively determined whether the Petitioners' products were faulty, whether the PPB has the authority to regulate the manufacture and standards of medical devices, whether this was the sole reason for W.H.O. to suspend the certification, whether the PPB were justified in sharing the report with W.H.O., what losses were actually incurred as a result of the suspension, whether the Internal Memo dated 4th December 2012 contained "doctored" pictures and false information, and to whom the Internal Memo and/or the GMP Inspection Report was circulated outside the Ministry of Health to the detriment of the Petitioners. Even assuming the court is able to overlook these gaps, the most pertinent issue that then emerges for determination is:

Whether the Pharmacy and Poisons Board had mandate to carry out the inspection and produce the report; and if the issue is answered in the negative, whether this ultra vires move is

a violation of the Petitioners' rights.

9. At this juncture it would be inevitable to ponder on a preliminary point of law – Does this issue constitute a Constitutional Issue, or is this a case of a Private Law matter disguised as a Constitutional Issue?

DETERMINATION

10. What is a constitutional issue? Nyamu, J (as he then was) in **Muiruri vs. Credit Bank Ltd & Another Nairobi HCMCS No. 1382 of 2003 [2006] 1 KLR 385** was of the view that “A constitutional issue ... is that which directly arises from court’s interpretation of the Constitution.” This court made similar determination in the case of **Maggie Mwauki Mtalaki vs. Housing Finance Company of Kenya [2015] eKLR** stating:

“52. The test whether a Petition raises a constitutional issue, and adopted by Tuiyott J in **FOUR FARMS LIMTIED vs. AGRICULTURAL FINANCE CORPORATION [2014] e KLR** following the decision in **DAMIAN BELFONTE vs THE ATTORNEY GENERAL of TRINIDAD AND TOBAGO** where it was stated inter....

... where there is a parallel remedy, Constitutional relief should not be sought unless the circumstances of which the complaint is made include some feature which makes it appropriate to take that course. As a general rule there must be some feature, which, at least arguably indicates that the means of least redress otherwise available would not be adequate. To seek constitutional relief in the absence of such feature would be a misuse, an abuse of the Court’s process.”

53. The above principle was not lost to the Court in **JOHN HARUN MWAU VS. PETER GASTROW & 3 OTHERS [2014] E KLR** where the court said –

“Courts will not normally consider a constitutional question unless the existence of a remedy depends on it; if a remedy is available to an applicant under some other legislative provision or some other basis, whether legal or factual, a court will usually decline to determine whether there has been in addition to a breach of the other declaration of rights.

... It is an established practice that where a matter can be disposed of without recourse to the Constitution, the Constitution should not be invoked at all. The court will pronounce on the constitutionality of a statute only when it is necessary for the decision of the case to do so.”

54. The Constitution is not to be invoked unless the constitutionality is itself in question, in **LEONARD JEFWA KALAMA AND ANOTHER vs. CONSOLIDATED BANK OF KENYA LTD. AND 3 OTHERS [2014] E KLR**, the court said-

“unless it can be shown that the law itself is against the constitution, the sale of charged property in accordance with due process of that law cannot be held to be unconstitutional deprivation of property within Article 40 of the constitution, this is because the constitution has as one of its principles of governance and national values under Article 10, the doctrine of the rule of law.”

11. The issue of whether the Petitioners’ rights were violated by the PPB overstepping their mandate will only become determinable upon establishing whether the PPB has indeed acted *ultra vires*. The constitutional issue therefore, if any, only arises as a conditional issue and may not in fact arise if the court finds that the PPB acted *intra vires* after all. The Supreme Court in **ICJ (K) v. A.G. & 2 Others S.C. Cri. Appeal No. 1 of 2012 on its part opined that the issue of enforcement of Bill of Rights should not be a collateral question when presented before the court. The Court did also adopt the Principle of Constitutional Avoidance in the case of **Communications Commission of Kenya & 5 others v Royal****

Media Services Limited & 5 others [2014] eKLR in the following terms:

“[256]...The principle of avoidance entails that a Court will not determine a constitutional issue, when a matter may properly be decided on another basis. In South Africa, in S v. Mhlungu, 1995 (3) SA 867 (CC) the Constitutional Court, Kentridge AJ, articulated the principle of avoidance in his minority Judgment as follows [at paragraph 59]:

“I would lay it down as a general principle that where it is possible to decide any case, civil or criminal, without reaching a constitutional issue, that is the course which should be followed.”

[257] Similarly the U.S. Supreme Court has held that it would not decide a constitutional question which was properly before it, if there was also some other basis upon which the case could have been disposed of (Ashwander v. Tennessee Valley Authority, 297 U.S. 288, 347 (1936)).”

12. For those reasons, the Petition fails the test of forum, and is hereby dismissed with a direction that each party bears its own costs.

13. There shall be orders accordingly.

Dated, Signed and Delivered in Mombasa this 10th day of July, 2015.

M. J. ANYARA EMUKULE

JUDGE

In the presence of:-

Miss Egessa holding brief Dr. Khaminwa for Petitioners

Miss Lutta for 1st – 3rd Respondents

No appearance for 4th Respondent

Mr. Kaunda Court Assistant