Omwando v Health & 6 others; Kingwara (Interested Party) (Constitutional Petition E037 of 2022) [2023] KEHC 3364 (KLR) (26 April 2023) (Ruling)

Neutral citation: [2023] KEHC 3364 (KLR)

REPUBLIC OF KENYA

IN THE HIGH COURT AT MOMBASA

CONSTITUTIONAL PETITION E037 OF 2022

OA SEWE, J

APRIL 26, 2023

IN THE MATTER OF ARTICLES 1, 2, 3, 10, 19, 20, 21, 22, 23, 27, 43, 46, 47, 50(1), 56, 73, 159, 165, 258 AND 259 OF THE CONSTITUTION OF KENYA, 2010

AND

IN THE MATTER OF THE HIV AND AIDS PREVENTION AND CONTROL ACT, 2006

AND

IN THE MATTER OF ABUSE AND ILLEGALITIES IN NATIONAL HIV ALGORITHM REVIEW AND THE REVISION OF QUALITY STANDARD THRESHOLD OF MALARIA DIAGNOSTIC KITS

BETWEEN

JOSEPHAT KAZEH OMWANDO ..... PETITIONER

AND

PRINCIPAL SECRETARY, THE MINISTRY OF HEALTH ..... 1ST RESPONDENT

THE CABINET SECRETARY, MINISTRY OF HEALTH ..... 2ND RESPONDENT

ATTORNEY GENERAL ..... 3RD RESPONDENT

HEAD, NATIONAL HEALTH LABORATORY SERVICES ..... 4TH RESPONDENT

HEAD, NATIONAL AIDS AND STI CONTROL PROGRAMME .... 5TH RESPONDENT

DIRECTOR OF MEDICAL SERVICES, PREVENTIVE AND PROMOTIVE HEALTH ..... 6TH RESPONDENT

HEAD, MALARIA CONTROL PROGRAMME ..... 7TH RESPONDENT

AND

LEONARD KINGWARA ..... INTERESTED PARTY

RULING

[1] The Notice of Motion dated August 19, 2022 was filed herein on August 25, 2022 by the petitioner under Sections 1A, 1B and 3A of the *Civil Procedure Act*, Chapter 21 of the Laws of Kenya and Order 5 Rule 17, Order 51 Rule 1 of the *Civil Procedure Rules* for orders that:

[a] Spent

[b] Spent

[c] The Court be pleased to issue conservatory orders staying the decision of the Ministry of Health to conduct a National HIV Algorithm Review pending the hearing and determination of the Petition;

[d] Spent

[e] The Court be pleased to issue conservatory orders against the Ministry of Health, its agents, assigns and/or representatives from altering the National HIV Testing Algorithm pending the hearing and determination of the Petition.

[f] Costs of the application be in the cause.

[2] The application was predicated on the grounds that the Kenyan National HIV testing is currently being conducted using a kit known as Determine HIV as the first line screening kit, and First Response as the confirmatory kit, while cases that require tie-breaking are referred to the laboratory for further scrutiny. It was further stated that the World Health Organization made a recommendation to its member states that a third kit be introduced into the national HIV testing algorithms; a measure that would provide swift and accurate results and negate the need for laboratory tests.

[3] The petitioner averred that, based on the recommendation aforementioned, Kenya started conducting tests for the purpose of making modifications to the National HIV Testing Algorithm, to pave way for the introduction of a third kit. At paragraph 6 of his grounds, the petitioner complained that, in the course of the review of the National HIV Testing Algorithm, the defendants did not conduct any sensitization on the sample donors with regard to collection of blood samples, the purpose of the exercise and the expected outcome of the clinical study to be carried out on the samples collected. He contended that the samples collected were inadequate as they were collected from only three health facilities in Nairobi, thereby disregarding the fact that the revised algorithm is intended to test and capture results in respect of the entire Kenyan populace.

[4] The petitioner further averred the Ministry of Health appointed one Leonard Kingwara (the interested party herein) as a member of the task force yet he is not a qualified medical laboratory technician. He alleged that the interested party conducted himself in an unprofessional manner while chairing a tender evaluation committee for a DUO Kit used in testing expectant mothers for HIV and Syphilis, leading to a stock-out of the products as the matter proceeded to the Public Procurement Administrative Review Board. Thus, the petitioner believes that the interested party's independence cannot be guaranteed in a scientific process that requires objectivity beyond self-agenda. He was also of the view that the whole

review process was being rushed in anticipation of changes in placements by the new government after the August 2022 general elections.

[5] The petitioner further stated that, other than the HIV programme, there is another plot to reduce the quality of Malaria testing kits by reducing the Panel Detection Score (PDS) for kits from 90% to 85% to accommodate a manufacturer's product whose PDS is less than 90%; yet Kenya is heading to the Malaria elimination stage and therefore needs to use products with higher sensitivity, so as to not reverse the gains made. He pointed out that, since the World Health Organization recommends a PDS of at least 90%, there would be no justification for opting for a lower PDS.

[6] The foregoing grounds were supported by the petitioner's averments in his affidavit sworn on August 19, 2022, to which he annexed a set of documents to augment his case.

[7] A response to the application was filed on September 12, 2022 by way of a Replying Affidavit sworn by Dr Patrick Amoth, the Acting Director General for Health at the Ministry of Health. He conceded that the WHO issued guidelines on HIV testing which included the use of the three-test algorithm where National HIV prevalence is less than 5% to increase the accuracy of HIV diagnosis. He averred that the WHO developed a generic protocol which was to be adapted by countries when determining what combination of kits best fit their respective circumstances. Dr Amoth further conceded that a task force was appointed by the Ministry of Health on March 22, 2022 to, among other things, review the available evidence to adapt the three-test algorithm as per the WHO recommendation. He pointed out that the taskforce is still undertaking its mandate.

[8] In response to the allegation that the collection of samples was not representative of the Kenyan populace, Dr Amoth averred that the collection of samples in 3 facilities was done in accordance with KNH-UON Ethical Review Committee and National Commission for Science, Technology and Innovation (NASCOTI) approved protocol and as per the WHO guidelines. He therefore asserted that the geographical area sample collection cannot affect the outcome of the study. He added that sensitization of all donors was done and informed consent was signed as per study protocol; and that the taskforce is transparent as evidenced by development of a study protocol.

[9] At paragraph 12 of his Replying Affidavit, Dr Amoth averred that Leonard Kingwara is not a member of the taskforce and therefore did not participate in the laboratory testing of any of the kits under study. He therefore asserted that the allegations against him in the petitioner's Supporting Affidavit are unfounded. He also denied that the Ministry of Health is intending to reduce the PDS for Malaria Kits to 85% as alleged by the petitioner. He added that the allegations are not only baseless but are meant to misguide the Court. According to Dr Amoth, the petitioner is evidently driven by business interests as opposed to the interests of the patients, health workers or the healthcare system as a whole. He accordingly prayed that the Notice of Motion dated August 19, 2022 be dismissed with costs.

[10] In response to the averments made in Dr Amoth's Replying Affidavit, the petitioner filed a Further Affidavit in which he reiterated his assertion that the interested party is a member of the taskforce. He exhibited documents to his Further Affidavit as Annexures "J K O 1", "J K O 2" and "J K O 3" to demonstrate that the interested party was one of the co-investigators. The petitioner also pointed out that, out of 11 members of the taskforce, 9 are from the Ministry of Health; and therefore that there was no representation from the development partners, including Global Fund and the U.S. President's Emergency Plan for AIDS Relief who have been funding the HIV programme for years. He also faulted the respondents for leaving out the civil societies representing people living with HIV as well as faith groups who play a critical role in representing the needs and interests of the vulnerable populations.

[11] Directions were thereafter given on September 22, 2022 that the application be canvassed by way of written submissions. It appears only counsel for the respondent complied. Thus, in her written

submissions filed herein on February 14, 2023, Ms Waswa relied on the Replying Affidavit filed on behalf of the respondents and the interested party and underscored the assertion that the process of the three-test algorithm was initiated on the directions of the WHO; a position confirmed by the petitioner himself. She therefore submitted that the Ministry of Health only appointed the taskforce to ensure compliance with the WHO directives; and that it is not clear how the petitioner is affected to warrant the issuance of conservatory orders.

[12] It was further the submission of Ms Waswa that the issues raised by the petitioner have nothing to do with the three-test Algorithm, the patients or medical practitioners affected by HIV. She therefore urged the Court to find that the petitioner's application lacks merit and that if anything, has been brought against the wrong parties.

[13] I have given careful consideration to the application, and in particular, the grounds relied on by the petitioner as explicated on the face of the application and in the two affidavits filed in support of the application. I have likewise considered the response filed on behalf of the respondents as set out in the Replying Affidavit sworn by Dr Amoth and the written submissions filed herein by their counsel. The underlying facts are not in dispute as the parties are in agreement that, following the recommendation of WHO to its member states, it was necessary for the Ministry of Health to introduce a third kit into the national HIV Testing Algorithms in order to provide swift and accurate results and negate the need for laboratory tests.

[14] It is further not in dispute that, based on the recommendation aforementioned, the Ministry of Health set up a taskforce to conduct tests for the purpose of making modifications to the National HIV Testing Algorithm and pave way for the introduction of a third kit. The list of members is not in dispute. However, at paragraph 6 of his grounds, the petitioner complained that, in the course of the review of the National HIV Testing Algorithm, the respondents did not conduct any sensitization targeting the sample donors with regard to collection of blood samples, the purpose of the exercise and the expected outcome of the clinical study to be carried out on the samples collected. He asserted that the samples collected were inadequate as they were collected from only three health facilities in Nairobi. Hence, the issue for determination is whether the petitioner has made out a good case for the grant of a conservatory order.

[15] At this stage, the Court need not examine the merits of the case closely. The need for caution was aptly expressed thus by Hon Ibrahim, J (as he then was) in the *Muslim for Human Rights & 2 Others v Attorney General & 2 Others* [2011] eKLR:

> " The court must be careful for it not to reach final conclusion and to make final findings. By the time the application is decided; all the parties must still have the ability and flexibility to prosecute their cases or present their defences without prejudice. There must be no conclusivity or finality arising that will or may operate adversely vis-à-vis the case of either party. The principle is similar to that in temporary or interlocutory injunctions in civil matters..."

[16] Similarly, in Nairobi High Court Petition No 16 of 2011: *Centre for Rights Education & Awareness (CREAW) & 7 Others v Attorney General*, the view was expressed that:

> " At this stage, a party seeking a conservatory order only requires to demonstrate that he has a prima facie case with likelihood of success and that unless the court grants the conservatory order, there is real danger that he will suffer prejudice as a result of the violation or threatened violation of *the Constitution*."

[17] In the same vein, the Supreme Court had the following to say in *Gatirau Peter Munya v Dickson Mwenda Githinji & 2 Others* (supra):

> "Conservatory orders bear a more decided public-law connotation; for these are orders to facilitate ordered functioning within the public agencies, as well as to uphold the adjudicatory authority of the Court, in the public interest. Conservatory orders, therefore, are not, unlike interlocutory injunctions, linked to such private party issues as "the prospects of irreparable harm" occurring during the pendency of a case or "high probability of success" in the Applicant's case for order of stay. Conservatory orders, consequently, should be granted on the inherent merit of a case, bearing in mind the public interest, the constitutional values and the proportionate magnitudes, and priority levels attributable to the relevant cases."

[18] Hence, it is now settled that an applicant for conservatory orders for purposes of Articles 22 and 23(3)(c) of the *Constitution* must satisfy the Court as to the following three considerations:

[a] That he/she has a prima facie case with a high likelihood of success;

[b] That the Petition will be rendered nugatory;

[c] That public interest weighs in his/her favour.

[19] What amounts to a *prima facie* case was aptly stated in *Mrao Ltd v First American Bank of Kenya Ltd & 2 Others* [2003] KLR 123 thus:

> "A prima facie case in a civil application includes but not confined to a genuine and arguable case. It is a case in which on the material presented to the Court a tribunal properly directing itself will conclude that there exists a right which has apparently been infringed by the opposite party as to call for an explanation or rebuttal from the latter."

[20] Similarly, in *Kevin K Mwiti & others v Kenya School of Law & others* (supra), it was held that:

> "A prima facie case, it has been held is not a case which must succeed at the hearing of the main case. However, it is not a case which is frivolous. In other words the Petitioner has to show that he or she has a case which discloses arguable issues and in this case arguable Constitutional issues. It has been held that in considering an application for conservatory orders, the court is not called upon to make any definite finding either of fact or law as that is the province of the court that will ultimately hear the petition. At this stage the applicant is only required to establish a prima facie case with a likelihood of success. Accordingly in determining this application, the Court is not required-indeed it is forbidden- from making definite and conclusive findings on either fact or law.

[21] With the foregoing in mind, I have considered the Petition in the light of the averments set out in the petitioner's Notice of Motion and its Supporting Affidavit. Issues have been raised about public participation, composition of the taskforce and compliance with best health practices as prescribed by WHO. These are not frivolous matters, noting the composition of the taskforce as per Annexure "PA 1" to the Replying Affidavit. And, although Dr Amoth contended that the interested party, Mr Leonard Kingwara, did not participate in the laboratory testing of any of the kits under study, there is indication to the contrary in the letters annexed to the petitioner's Further Affidavit.

[22] Moreover, with regard to public participation, a key tenet of Article 10 of the *Constitution*, a three-judge bench of the High Court in *Mui Coal Basin Local Community & 15 Others v Permanent Secretary Ministry of Energy & 17 Others* [2015] eKLR held:

> ...A public participation programme, must...show intentional inclusivity and diversity. Any clear and intentional attempts to keep out bona fide stakeholders would render the public participation programme ineffective and illegal by definition. In determining inclusivity in the design of a public participation regime, the government agency or Public Official must take into account the subsidiarity principle: those most affected by a policy, legislation or action must have a bigger say in that policy, legislation or action and their views must be more deliberately sought and taken into account."

[23] Thus, the petitioner's assertion that the respondents ought to have involved the concerned representatives of the civil society and faith-based groups as well as the key donors in the HIV health care sector is not a frivolous assertion. I am likewise satisfied that the public interest aspect of the matter has been satisfactorily demonstrated by the petitioner, bearing in mind that "public interest", according to Black's Law Dictionary, is defined as:

> " The general welfare of the public that warrants recognition and protection; or something in which the public as a whole has a stake especially an interest that justifies governmental regulation."

[24] I am therefore satisfied a prima facie case has been made out by the petitioner, judging by the material presented by the plaintiff vide his application and the response thereto by the respondents. In the premises, I find merit in the petitioner's application dated August 19, 2022. The same is hereby allowed and orders granted as hereunder:

[a] That a conservatory order be and is hereby granted staying the decision of the Ministry of Health to conduct a National HIV Algorithm Review pending the hearing and determination of the Petition;

[b] That a conservatory order be and is hereby granted against the Ministry of Health, its agents, assigns and/or representatives restraining them from altering the National HIV Testing Algorithm pending the hearing and determination of the Petition.

[c] That costs of the application be in the cause.

It is so ordered.

DATED, SIGNED AND DELIVERED VIRTUALLY AT MOMBASA THIS 26TH DAY OF APRIL 2023

OLGA SEWE

JUDGE