



REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA AT NAIROBI

MISCELLANEOUS CIVIL APPLICATION NO. 391 OF 2017.

IN THE MATTER OF AN APPLICATION FOR JUDICIAL REVIEW

ORDERS OF CERTIORARI.

AND

IN THE MATTER OF AMENDMENT OF SECTIONS 35A(5) & 35I(b) OF THE PHARMACY AND POISONS ACT UNDER THE CLINICAL OFFICERS (TRAINING, REGISTRATION AND LICENSING) BILL, 2016

AND

IN THE MATTER OF PHARMACY & POISONS ACT AND CLINICAL OFFICERS (TRAINING, REGISTRATION AND LICENSING) BILL, 2016

AND

IN THE MATTER OF ARTICLES 21, 43, 109, 110, 113 118, 122 & 123 OF THE CONSTITUTION OF KENYA

AND

IN THE MATTER OF SECTION 133 OF THE STANDING ORDERS OF THE NATIONAL ASSEMBLY ON COMMITTEE STAGE

AND

IN THE MATTER OF THE DECISION ON 5TH APRIL, 2017

BY THE 1ST & 2ND RESPONDENTS TO PERMIT INTRODUCTION OF AMENDMENT TO PHARMACY AND POISONS ACT WITHIN CLINICAL OFFICERS' BILL 2016 AT COMMITTEE STAGE AND PASSAGE AND SUBSEQUENT ASSENT INTO LAW

BETWEEN

REPUBLIC.....APPLICANT

VERSUS

THE NATIONAL ASSEMBLY.....1ST RESPONDENT

THE SPEAKER OF NATIONAL ASSEMBLY.....2ND RESPONDENT

THE SPEAKER OF SENATE.....3RD RESPONDENT

THE HON. ATTORNEY GENERAL.....4TH RESPONDENT

EX PARTE: DR. GEORGE WANG'ANG'A

RULING

Introduction

1. On 29th June, 2017, I granted to the applicant herein, **Dr. George Wang'ang'a**, leave to commence judicial review proceedings in the manner sought in the Chamber Summons dated 27th June, 2017. Pursuant to the proviso to Order 53 rule 1(4) of the *Civil Procedure Rules*, I however directed that the issue of leave operating as a stay be heard inter partes and it is that direction that is the subject of this ruling.
2. According to the ex arte applicant, the *Clinical Officers (Training, Registration and Licensing) Bill, 2016* was assented into law on 21st June, 2017. It was a Private-member's Bill and was passed by the National Assembly on 5th April, 2017 and makes provision for training, registration and licensing of Clinical Officers; to regulate their practice and to provide for the establishment, powers and functions of the Clinical Officers Council. The new law repeals and replaces the existing *Clinical Officers (Training, Registration and Licensing) Act*, Cap. 260 of the Laws of Kenya.
3. According to the ex parte applicant, section 34 of the said Bill amends sections 35A (5) and 35I (b) of the *Pharmacy and Poisons Act* (Cap. 244) of the Laws of Kenya: This amendment to the *Pharmacy and Poisons Act* were inserted by the National Assembly in the Bill during the Committee Stage amendments to the Bill through a notice of Motion.
4. It was the ex parte applicant's contention that the substantive amendment to the *Pharmacy and Poisons Act* in the Bill is a different subject matter and unreasonably or unduly expands the subject of the Bill and is not in logical sequence to the subject matter of the Bill. It was contended that the existing legislation, section 35I (b) of the *Pharmacy and Poisons Act*, partly fulfilled the requirements of the Article 21 of the constitution, as a means of anchoring an internationally accepted standard quality control system for provision of quality, efficacious and safe medicines and that this was appreciated by this Court in High Court at Nairobi in **Misc. Civil Appli. No. 159 of 2016**.
5. According to the applicant, whereas the aim and or motivation of the amendment was to transfer the Good Manufacturing Practices (GMP) inspection functions from the National Quality Control Laboratory to the Pharmacy and Poisons Board, the resultant imminent danger of exposure of Kenyan citizens to dangerous substandard and counterfeit medicines due to the deletion of section 35I(b) would have been mitigated had the National Assembly opted for substitution of the Director of National Quality Control Laboratory with the Pharmacy and Poisons Board, like was with section 35A (5), so as to retain the international certification system for control of manufacture of medicines.
6. It was contended that the Chief of Staff and Head of Public Service, **Dr. Joseph K. Kinyua**, vide letter Ref: SH/9/7 Vol (18), on 18th April, 2017, wrote to the Attorney General **Hon. Prof Githu Muigai** requesting him to prepare an appropriate memorandum to the President, advising him not to sign the Bill into law in its current form.
7. According to the applicant, once the impugned Bill was passed by National Assembly, the bill should have been submitted to the Senate for consideration, in line with Articles 109, 110 to 113, 122 and 123 of the constitution and the Standing Orders of the Houses.

8. It was the ex parte applicant's case that the stated amendment of sections 35A(5) and 35I(b) to the **Pharmacy and Poisons Act** in the **Clinical Officers (Training, Registration and Licensing) Bill, 2016**, if allowed, would have an unintended repeal of the above section 35D of the **Pharmacy and Poisons Act**, by implication thus un-procedurally abolishing the National Quality Control Laboratory and create a lacuna for unscrupulous manufacture of counterfeit and substandard medicines.

9. The applicant further contended that a function conferred by statute cannot be transferred by the depository or by anybody else without statutory authority. It was disclosed that sections 26 and 27 of the **State Corporations Act (Cap. 446)** establishes the State Corporations Advisory Committee whose mandate, in consultation with the Attorney-General and the Treasury, is to among other things, advise the President on the establishment, reorganization or dissolution of State Corporations. In his view, section 34 in the **Clinical Officers (Training, Registration and Licensing) Bill, 2016**, amending sections 35A(5) and 35I(b) of the **Pharmacy and Poisons Act**, deals with a different subject and proposes to unreasonably or duly expand the subject of the Bill and is not in logical sequence to the subject matter of the Bill. In his view, although a proposed law may cover a broad canvas and perhaps may require consequential amendments to a considerable number of other written laws, the nature of its subject matter should give it a fundamental coherence. However, the **Clinical Officers (Training, Registration and Licensing) Bill, 2016**, lacks that fundamental coherence.

10. It was further contended that because section 34 in the **Clinical Officers (Training, Registration and Licensing) Bill, 2016**, which amended sections 35 A (5) and 35 I (b) of the **Pharmacy and Poisons Act**, was introduced at the Committee stage of the whole house, public participation that include key interested parties and stakeholders like State Corporations Advisory Committee and Pharmaceutical experts, among others, was completely excluded from the processes in express violation of the provision of Articles 10 and 118(1) (b) of the constitution.

11. According to the applicant, in 2009, an officer of the Pharmacy and Poisons Board issued medicines import permit for importation of several containers of counterfeit medicines from China that were intercepted by officials of National Quality Control Laboratory. Further, the Efficiency Monitoring Unit (EMU) Report of 2011 on Pharmacy and Poisons Board confirmed that the Pharmacy and Poisons Board allowed importation of medicines from an Indian company which had failed its own compliance certification to Good manufacturing Practices. The above said report further revealed that the Pharmacy and Poisons Board, nonetheless, registered medicines that failed the analytical sample testing of the National Quality Control laboratory.

12. The applicant revealed that Kenya is a regional herb for Manufacturing of medicines and that there are over 40 local Pharmaceutical Manufacturing Companies and most of the medicines are sold out of the Country. In order to sell/tender medicines in or out of Kenya, the buying countries and institutions require Compliance certificate to the GMP as a technical requirement from supplying Countries or institutions and even internally, for instance, Kenya Medical Supplies Authority (KEMSA) requires compliant certificate to GMP in order to supply medicines.

13. It was therefore the applicant's contention that the inadvertent deletion of section 35I(b) render the manufacturers of medicines out of market hence loss of jobs and closure of the affected companies.

14. The application was supported by the 3rd interested party.

1st Interested Party's Case

15. The applicant was opposed by the 1st interested party herein, **the Pharmacy & Poisons Board** (hereinafter referred to as "the Board").

16. According to the Board, pursuant to the Board's legal mandate as stated hereinabove, the Board has been carrying out inspections of pharmaceutical manufacturing premises since implementation of Rule 10 of the **Pharmacy and Poisons (Registration of Drugs) Rules** to ensure that licensed manufacturers are compliant with the Good Manufacturing Practices (GMP) prescribed by the Board. However, in 2016, the

Board's mandate to inspect premises was challenged on the basis of section 35A (5) and 35 I (b) of the ***Pharmacy and Poisons Act*** in ***Judicial Review Division Miscellaneous Civil Application No. 159 Of 2016: R vs Pius Wanjala Ex Parte Ministry of Health & 5 Others*** in which this Court interpreted the 3rd Interested Party's mandate and the Board's mandate under the Act as being complementary.

17. The Board averred that being cognizant of the far reaching effects of the judgement, Parliament, in enacting the ***Clinical Officers (Training, Registration And Licensing) Act, 2017*** (hereinafter referred to as "the Clinical Officers' Act, 2017") amended section 35A (5) and 35 I (b) of the ***Pharmacy and Poisons Act*** to empower the Board or any other persons mandated by the Board to enter and sample any medicinal substance under production in any manufacturing premises and certify that the method of manufacture approved by the Board is being followed. The separate powers of the Director of NQCL as separate from the Board under Section 35 I (b) were also removed to align functions and ensure clarity on roles and responsibilities between the Board and the 3rd Interested Party.

18. The Board therefore disabused the notion that there will be a vacuum if a stay is not granted in the manner sought by the Applicant as prior to the referenced judgement and the amendment of the section 35A (5) and 35 I (b) of the Pharmacy and Poisons Act by the ***Clinical Officers' Act, 2017*** the Board carried out all the inspections necessary to ensure that medicines manufactured in or entering the Country are safe for consumption.

19. It was its view that before assenting to the ***Clinical Officers Act***, His Excellency (H.E.) The President sought, through the Office of the Head of the Public Service, and received advise from the Hon. Attorney General who confirmed that the said ***Clinical Officers Act*** was properly legislated and was constitutional.

20. It was also contended that in June 2017 H.E. the President assented to the ***Health Act, 2017***, and based on the provisions of the said Act there is no basis whatsoever for the Order of stay sought, as there is no imminent danger or threat either as alleged by the Applicant or at all. To the Board, no infringement of Article 43 of the Constitution will be occasioned to the general public by the time the Application is heard and determined and in any event, there is a presumption of Constitutionality of Laws enacted by Parliament, which this Honourable Court has to consider prior to suspending a law enacted by Parliament and already in force.

21. It was therefore contended that an order of stay is not efficacious in the circumstances of this matter as the same will not only create a lacuna in the regulation of medicines but it will also amount to an interference in the powers of the legislature and the mandate entrusted to the Board without giving the parties an adequate opportunity to be heard on the merits of the Judicial Review Application. In the Board's view, the decision to amend sections 35A (5) and 35 I (b) of the ***Pharmacy and Poisons Act*** by the ***Clinical Officers' Act, 2017*** having been made and the said Act having come into force there is no decision capable of being stayed in the manner sought by the Applicant.

22. The Board took the view that in an application for leave to apply for judicial review and stay, as in the present circumstances, this Honourable Court has to be careful in what it states lest it touches on the merits of the main application for judicial review and the Applicant herein is inviting the Court to look into the merits of the case in seeking the stay in the manner sought. According to it, staying the implementation of the impugned amendments under the ***Clinical Officers' Act, 2017*** will not only affect the legal mandate of the Board but will also jeopardize day to day operations of the Board and this Court ought to consider the proportionality of the decision of stay it is presently being invited to make. In addition, staying the Implementation of amendments will lead to a reversion to a state of confusion as opposed to a state of clarity and certainty that has been introduced to the ***Pharmacy and Poisons Act*** by the amendments contained in the ***Clinical Officers Act***.

23. The Board therefore urged that prayer 3, 4 and 5 in the Applicant's Chamber Summons Application dated June 27, 2017 should not issue and the same should be dismissed forthwith.

1st and 2nd Respondents' Case

24. The application was similarly opposed by the 1st and 2nd Respondents herein, the National Assembly and its Speaker respectively.

25. Apart from dealing with the merits of the challenged decision, the 1st and 2nd Respondents averred that the applicant's application contravenes the principles of presumption of constitutionality of legislation enacted by parliament and therefore the court should not entertain the same. In their view, as the applicant has not made out a prima facie case of unconstitutionality of the Bill, accordingly the Applicant does not deserve the order to stay the implementation of the Act.

26. In the 1st and 2nd Respondents's view, the application is also a threat to the doctrine of separation of powers and is an encroachment to the legislative mandate of parliament and that an order by the court granting the petitioner's prayer would be a negation of the doctrine of separation of powers and this would be an interference of parliament's constitutional powers, by the judiciary. According to them, the orders sought by the applicant is tantamount to asking the Court to amend or repeal a piece of legislation.

27. It was therefore the 1st and 2nd Respondents's urging that this Court ought not to exercise its discretion to grant the orders sought in the said application as the applicant has not adduced any or any cogent consumption of counterfeit or substandard medicines as a result of implementation of the act and specifically section 35A.

28. The Court was therefore urged to find that the chamber summons application herein lacks merit, it is frivolous, generally argumentative and an outright abuse of the court process and merely intended to stifle the 1st and 2nd respondents' mandate to legislate. Further, it would occasion grave prejudice to the 1st and 2nd respondent's if any of the orders sought in the said application are granted in the applicant's favour.

29. That in the circumstances, of this case for the interests of justice, fairness and proportionality to be met, I pray that the application for stay of implementation of Sections 35 A (5) and 35 I (b) b dismissed.

30. The 2nd interested party also supported the application.

Determinations

31. I have considered the issues raised before me in respect of the instant application. As leave had been granted, the only issue for determination is stay. Therefore whereas the parties in this application dealt with the substance of the application I will not deal with the same.

32. It is however clear that the effect of the grant of the stay sought herein is to temporarily suspend legislation.

33. In **Kizito Mark Ngaywa vs. Minister of State for Internal Security and Provincial Administration & Anor [2011] eKLR**, Ibrahim, J (as he then was) referred to his own decision in **Bishop Joseph Kimani & 2 Ors vs. The Hon Attorney General & Ors [2010] eKLR** in which he pronounced himself as follows:

“It is a very serious legal and Constitutional step to suspend the operation of statutes and statutory provisions. The courts must wade with care, prudence and judicious wisdom. For the High Court to grant interim orders in this regard, I think one must at the interlocutory stage actually show that the operation of the legislative provision are a danger to life and limb at that very moment...It is my view the principle of presumption of Constitutionality of Legislation in (sic) imperative for any state that believes in democracy, the separation of powers and the Rule of Law in general. Further the courts to be able to suspend legislation during peace times where there is no national disaster or war, would in my view be interfering with the independence and supremacy of Parliament in its Constitutional duty of legislating law. I think that I shall hold the said views and that legislation should only be impugned in any manner only where it has been proven to be unconstitutional, null and void.

Conservancy orders to suspend operation of statutes, statutory provisions or even Regulations should be wholly avoided except where the national interest demand and the situation is certain...I am still of the view that “there is no place for conservatory or interim order in petitions, which seek to nullify or declare legislation/statutes unconstitutional, null and void.” It is even more premature at this stage where the application has not been heard or is not being heard to seek such conservatory orders. The applications must be heard first.”

34. This position is in line with the principle enunciated in the Supreme Court of India case in **Hambardda Wakhana vs. Union of India Air [1960] AIR 554** that:

“In examining the constitutionality of a statute it must be assumed the Legislature understands and appreciates the needs of the people and the law it enacts are directed to problems which are made manifest by experience and the elected representatives assembled in a Legislature enacts laws which they consider to be reasonable for the purpose for which they are enacted. Presumption is therefore in favour of the constitutionality of an enactment.”

35. This position was affirmed by the Court of Appeal of Tanzania in the celebrated case of **Ndyanabo vs. Attorney General [2001] EA 495** which was a restatement of the law in the English case of **Pearlberg vs. Varty [1972] 1 WLR 534**. In the former, the Court held that:

“Until the contrary is proved, a legislation is presumed to be constitutional. It is a sound principle of constitutional construction that, if possible, a legislation should receive such a construction as will make it operative and not inoperative”

36. This was Majanja, J’s view in **Susan Wambui Kaguru & Ors vs. Attorney General Another [2012] KLR**, where the learned Judge took the following viewpoint:

“I have given thought to the arguments made and once again I reiterate that every statute passed by the legislature enjoys a presumption of legality and it is the duty of every Kenyan to obey the very laws that are passed by our representatives in accordance with their delegated sovereign authority. The question for the court is to consider whether these laws are within the four corners of the Constitution. No doubt serious legal arguments have been advanced and I think any answer to them must await full argument and consideration by the court. I cannot at this stage make an interim declaration which would effectively undo the legislative will unless there are strong and cogent reasons to do so.”

37. What clearly comes out is that the power to suspend legislation during peace time ought to be exercised with care, prudence and judicious wisdom where it is shown that the operation of the legislative provision are a danger to life and limb at that very moment and where the national interest demand and the situation is certain. On my part I would modify that view by adding to the phrase “a danger to life and limb” the words “or where there is imminent danger to the Bill of Rights” since Article 19(1) of the Constitution provides that the “Bill of Rights is an integral part of Kenya’s democratic state and is the framework for social, economic and cultural policies” and Article 21(a) provides that “it is a fundamental duty of the State and every State organ to observe, respect, protect, promote and fulfil the rights and fundamental freedoms in the Bill of Rights.”

38. In other words where there are strong and cogent reasons conservatory orders may be granted.

39. In this case from the ex parte applicant’s case for stay as supported by the 3rd interested party is that amendment of sections 35A(5) and 35I(b) to the ***Pharmacy and Poisons Act*** in the ***Clinical Officers (Training, Registration and Licensing) Bill, 2016***, if allowed, would have an unintended repeal of the above section 35D of the ***Pharmacy and Poisons Act***, by implication thus un-procedurally abolishing the National Quality Control Laboratory and create a lacuna for unscrupulous manufacture of counterfeit and substandard medicines.

40. This position is vehemently opposed by the Respondents and the interested parties who oppose the

application. To them, there will be no vacuum if a stay is not granted in the manner sought by the Applicant as prior to the referenced judgement and the amendment of the section 35A (5) and 35 I (b) of the *Pharmacy and Poisons Act* by the *Clinical Officers' Act, 2017* the Board carried out all the inspections necessary to ensure that medicines manufactured in or entering the Country are safe for consumption hence there is no basis whatsoever for the Order of stay sought, as there is no imminent danger or threat either as alleged by the Applicant or at all. To the Board, no infringement of Article 43 of the Constitution will be occasioned to the general public by the time the Application is heard and determined hence an order of stay is not efficacious in the circumstances of this matter as the same will not only create a lacuna in the regulation of medicines.

41. It is clear that the parties herein have taken diametrically opposed positions in the matter. It is my view that this is not the kind of matter that the Court can definitely describe as “certain”.

42. It is therefore my view that no satisfactory material has been placed before me to resort to the drastic remedy of suspending the legislation the subject of these proceedings.

43. In the premises I decline to direct that the leave which was granted herein operates as a stay.

44. The costs will be in the cause.

45. Orders accordingly.

Dated at Nairobi this 31st day of July, 2017

G V ODUNGA

JUDGE

Delivered in the presence of:

Miss Motabori for Mr Simiyu for the applicant

Mr Sisule for the interested party

CA Mwangi