



REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA AT NAIROBI

MISCELLANEOUS CIVIL APPLICATION NO. 159 OF 2016.

IN THE MATTER OF: AN APPLICATION FOR LEAVE TO APPLY FOR JUDICIAL REVIEW ORDERS OF CERTIORARI, PROHIBITION AND MANDAMUS.

AND

IN THE MATTER OF: THE PHARMACY AND POISONS ACT, (CAP.244), LAWS OF KENYA

AND

IN THE MATTER OF: ARTICLE 43 OF THE CONSTITUTION OF KENYA

AND

IN THE MATTER OF: THE DECISION ON 10TH MARCH, 2016 BY THE 3RD RESPONDENT TO STOP NATIONAL QUALITY CONTROL LABORATORY FROM PERFORMING ITS STATUTORY FUNCTION

BETWEEN

DR. PIUS WANJALAAPPLICANT

VERSUS

MINISTRY OF HEALTH.....1ST RESPONDENT

DR. CLEOPA MAILU,

CABINET SECRETARY, MINISTRY OF HEALTH.2ND RESPONDENT

DR. NICHOLAS MURAGURI, PRINCIPAL SECRETARY,

MINISTRY OF HEALTH.....3RD RESPONDENT

PHARMACY & POISONS BOARD.....4TH RESPONDENT

NATIONAL QUALITY CONTROL LABORATORY.5TH RESPONDENT

THE HON. THE ATTORNEY GENERAL.....6TH RESPONDENT

RULING

1. By a Chamber Summons dated 4th April, 2016, the ex parte applicant herein, **Dr. Pius Wanjala**, applied for the following orders:
 1. **THAT** this Court be pleased to grant leave to the Applicant to apply for the Order of *Certiorari* to have the decision of the Principal Secretary of Ministry of Health vide circular Ref: MOH/ADM/1/2/17/VOL.I of 10th March, 2016, which was copied to 2nd Respondent, stopping the National Quality Control Laboratory from performing the functions conferred by Section 35 A (5) and 35 I (b) of the Pharmacy and Poisons Act, CAP 244 Laws of Kenya, removed into the High Court for purposes of its being quashed;
 2. **THAT** this Court be pleased to grant leave to the Applicant to apply for the Order of *Certiorari* to have the Gazette Notices 147 of 1981, 142 of 1991 and any other Gazette Notice that Gazetted, as regards and relates to, Rule 10 of the Pharmacy and Poisons (registration of drugs) Rules, removed into the High Court for purposes of its being quashed;
 3. **THAT** this Court be pleased to grant leave to the Applicant to apply for the Order of Prohibition prohibiting the 4th Respondent (Pharmacy and Poisons Board) from acting upon the 3rd Respondent's circular of 10th March, 2016 of purporting to usurp the functions of National Quality Control Laboratory of; *inspecting premises and issuing certificates of compliance to Good manufacturing practices (GMP); by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being followed* as provided for in Sections 35 A (5) and 35 I (b) of the Pharmacy and Poisons Act, CAP 244 laws of Kenya, as well as those under section 35D of analytical testing of medicinal samples;
 4. **THAT** this Court be pleased to grant leave to the Applicant to apply for an Order of Mandamus compelling the 5th Respondent (National Quality Control Laboratory) to *inspect premises and issue certificates of compliance to Good manufacturing practices (GMP); by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being followed*; as provided in sections 35 A (5) and 35 I (b) of the Pharmacy and Poisons Act, CAP 244;
 5. **THAT** the grant of leave does operate as a stay of the decision, directives and acts of the 3rd Respondent contained in his circular Ref: MOH/ADM/1/2/17/VOL.I of 10th March, 2016 until the determination of the application herein or until the Honorable Judge orders otherwise.
 6. **THAT** the costs of this Application be provided for.
2. The Application was based on the following grounds:
 1. **The Applicant, together with the General Public are in grave danger of consuming substandard and counterfeit medicines due to the 3rd Respondents action of stopping the National Quality Control Laboratory from *inspecting premises and issuing certificates of compliance to Good manufacturing practices (GMP); by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being followed*, which action also infringes on the fundamental Right to the highest attainable standard of health, under article 43 of the Constitution, which is largely attained through access to quality medicines after laboratory tests; as opposed to Rule 10 of the Pharmacy and Poisons (Registration of Drugs) Rules which does not require the Pharmacy and Poisons Board to sample any medicinal substance under production in any manufacturing premises and test the samples in order to certify that the approved method of manufacture is being followed as it merely states thus; “*The Board may, before issuing a certificate of registration under these Rules, cause the premises in which the manufacturing of the drug is proposed to be conducted to be inspected by inspectors appointed for that purpose, and the inspectors shall have powers to enter the premises and inspect the plant and the process of manufacture intended to be employed in the manufacturing of the drug and make a report to the Board*”;** as well as upholding the dignity of this Honourable Court and the Supremacy of

the Constitution;

2. **The 3rd Respondent has elected to unprocedurally, unconstitutionally and illegally apply Rule 10 of the Pharmacy and Poisons (Registration of Drugs) Rules that is expressly inconsistent with express provisions of sections 35 A (5) & 35 (I) of the Pharmacy and Poisons Act, CAP 244 thereby using the aforesaid Rule 10 to set aside the corresponding statute;**
 3. **The application of the said Rule 10 of the Pharmacy and Poisons (Registration of Drugs) Rules in the terms directed by the 3rd Respondent's decision vide circular Ref: MOH/ADM/1/2/17/VOL.I of 10th March, requires the Secretariat to submit the inspections report to the Board for endorsement, which Board is non-existent and therefore it contravenes the order of this Court issued in *High Court Miscellaneous Application No. 402 of 2015* on 18th November, 2015, that suspended all activities that require the endorsement of the Board until such time that the said Board is constituted;**
 4. **The Applicant contends that the 3rd Respondent has acted irresponsibly, arbitrarily, capriciously, unreasonably, unprocedurally and his conduct is aimed at strangling the Quality Control Systems of Medicines (National Quality Control Laboratory) for ulterior motives thus frustrating the Applicant's legitimate expectation that the law that is meant to guarantee quality medicines is implemented;**
 5. **If stay is not granted there is real and present danger or likelihood that the Applicant and the General Public will be caused irreparable harm on consumption of medicines that are not certified through sampling and subsequent laboratory testing, by the time the application is heard and determined.**
 6. **This Application is made *bonafides*, without delay and in the best interests of justice and fairness.**
3. The Applicant relied on section 35 A (5) of the *Pharmacy and Poisons Act*, CAP 244.
 4. To the Applicant, this usurpation of the role of the National Drug Quality Control Laboratory and purporting to confer the same to the Pharmacy and Poisons Board is effectively in excess of the mandate of the 3rd Respondent as stipulated in *Pharmacy and Poisons Act*, Cap 244, thus amounting to substantive ultra vires.
 5. It was further contended that the 3rd Respondent abused his power by purporting to amend and or replace sections 35A(5) and 35I(b) of the *Pharmacy and Poisons Act*, Cap 244 with Rules. Whereas the 2nd Respondent is empowered to be consulted by the Board of Management on matters of finances and terms and conditions of employees, it was contended that there are legal limitations to the power of the 2nd and 3rd Respondents, and the said Respondents have broken loose from their mandate. In the Applicant's view, the Respondents should have implemented the findings of EMU report but chose to ignore the same.
 6. The Applicant added that the 3rd and 2nd Respondents permitted themselves to consider irrelevant factors that included:
 - a. Taking into consideration the Subsidiary law, Rule 10 of the Pharmacy and Poisons (registration of drugs) Rules, which is a nullity by virtue of being inconsistent with Section 35 A (5) and 35 I (b) of CAP 244;
 - b. That in the rest of East African Community, the inspection of Pharmaceutical Manufacturing Premises for purposes of compliance certification of Good manufacturing practices (GMP) is carried out by Regulatory authorities and so is Pharmacy and Poisons Board. The true position is that in Kenya there two complementary but independent Regulatory medicines authorities; Pharmacy and Poisons Board and National quality Control Laboratory;
 - c. Any other global desirable system should be addressed through Parliamentary legislation.
 7. Further the Applicant asserted that the 3rd Respondent refused to exercise discretion reasonably by purporting to overthrow a statutory Act of Parliament using a subsidiary law and though the 3rd Respondent is expected to implement the findings of EMU report, he chose to ignore the same.

8. To the Applicant therefore, the 3rd and 2nd Respondents demonstrated bad faith by electing to apply the Rules that expressly contravenes express statutory provisions meant to protect the public from harmful medicines and also by refusing to invite the Attorney General who offered to advise the Ministry on the true position of the law and further, by ignoring the correct decision of the Board of Management of NQCL.
9. The Applicant in addition averred that the 3rd Respondent had demonstrated lethargy to follow due process by usurping the function of the Director of NQCL and Board of management of NQCL and purporting to confer it to the Pharmacy and Poisons Board. To the Applicant, the decision by the 3rd and 2nd Respondents violated the principle of legitimate expectation in that both the Director and Board of Management expected the said Respondents to support them in their course of applying the provisions of the law but instead sabotaged the same.
10. The Applicant's case was that though the Respondent was required to uphold the principles of natural justice, this was violated by the Respondent being the judge of his own cause when he failed to invite the Attorney General for his legal opinion. To the Applicant, the 3rd Respondent was clearly biased against National quality Control laboratory in his decision.
11. After hearing Counsel for the Applicant on 5th April, 2016, I found that the grounds which the applicant intended to canvass at the substantive hearing disclosed prima facie case and I accordingly, proceeded to grant the ex parte applicant leave to commence judicial review proceedings. As the legality of the challenged decision was in question, I directed that the grant of leave would operate as stay of the said decision pending the hearing and determination of the substantive motion.
12. By applications dated 19th April, 2016 and 21st April, 2016, the 3rd and 4th Respondents (hereinafter referred to as "the Applicants") respectively applied for the setting aside, discharge and/or variation of the orders of stay of stay granted herein.
13. According to the Applicants, upon obtaining the ex parte orders, the 5th Respondent together with the applicant who is its Deputy Director embarked on the process of openly abusing the same by directing the pharmaceutical manufacturers that the court ordered it to do both local and foreign GMP. According to the Applicants, the said order did not give the 5th Respondent powers to start the process of conducting Good Manufacturing Practice (GMP) but only stay the circular from the 3rd Respondent ref-MOH/ADM/1/2/12/VOL.1 dated 10th March 2016. However, the director of the 5th Respondent embarked on sending letters to the Federation of Kenya Pharmaceutical Manufacturers purportedly calling for a meeting for purposes of briefing the industry on inspections schedule and logistics for Good Manufacturing Practice (GMP). Further, the 5th Respondent vide letter dated 12th April informed a manufacturer of an intended GMP inspection at their premises slated 9th May 2016.
14. It was contended that since the applicant herein is working with 5th Respondent as Senior Deputy Director, he is an interested party and cannot claim to be acting for the interest of public.
15. To the Applicants, as a result of the said confusion emanating from wrong interpretation of the said court order by the applicant together with the 5th respondent, there is a great risk to the general public consuming dangerous and sub-standard medicine and drugs. The Applicants disclosed that the ex parte order for stay issued on 5th April 2016 by the Court which has been wrongly interpreted by the applicant and the 5th Respondent is almost crippling the operations of the 4th Respondent and unless the same is set aside and/or discharged the operations of the 4th Respondent will be grounded exposing the public to great danger of consuming dangerous and substandard medicines.

Ex Parte Applicant's Case

16. In opposition to the application, the ex parte applicant filed the following grounds of opposition:
 - a. **The Instant Notice of Motion is improperly filed by the firm of Prof. Kiama Wangai & Company Advocates who have mistakenly entered appearance, a procedure that is not recognized in such proceedings;**

- b. That in any event, the Hon. The Attorney General is better placed to appear for the 3rd Respondent as opposed to the firm purportedly on record;
- c. There is no nexus between the provisions of law under which the application has been brought and the prayers sought wherefore the said application is bare and fatally defective as this honorable Court has not been moved properly;
- d. Further, the aforesaid application is NOT supported by a valid affidavit, see (*Order 19 rule 3 and 4*) which order is imported to judicial proceeding with respect to the law as to affidavits. That without disclosing source of authority, the affidavit is sworn by one Prof. Kiama Wangai who is not a party to these proceedings;
- e. Whereas the application is a Notice of Motion, the same is couched in the manner of a Chamber Summons application;
- f. That considering the totality of the application question, though brought purportedly on behalf of the 3rd Respondent, the same effectively speaks on behalf of the 4th Respondent and as such the application is bad in law and ought to be struck off.

17. It was further averred by the ex parte applicant that based on the aforesaid grounds, the application is fatally defective. It was further contended that the instant application is incurably defective as there is completely no nexus between the grounds of the application and the substantive prayer sought in that whereas the prayer sought is for variation of stay order granted, the grounds are geared towards alleged misinterpretation of the stay order granted.

18. To the ex parte applicant, if the Applicant's only issue is the alleged misinterpretation of the Court order of 5th April, 2016, then the logical prayer to this Honorable Court is for the Court to clarify the said Order as opposed to variation. To him, the aforesaid Court Order of 5th April, 2016 has not been misinterpreted as alleged by the 5th Respondent and himself as the 3rd Respondent has not even bothered to provide what he holds to be a true interpretation and has not cared to provide an alternative or "correct" interpretation of the same to this Honorable Court.

19. While appreciating that both the 4th Respondent and the 5th Respondent are complimentary National Medicines/drugs Regulators, by inference of their respective statutory functions, the ex parte applicant contended that the term Regulator or any of its derivatives is not in any way used in the entire *Pharmacy and Poisons Act*, CAP 244, as reference to any of the two said National regulatory bodies. The ex parte applicant disclosed that currently, there is a phenomenal upsurge of extreme cases of substandard and or counterfeit medicines that cake or mold in government facilities, some after having been dispensed to innocent Kenyans, after supplies by Kenya Medical Supplies Authority (KEMSA), which is in turn supplied by foreign and local manufacturers.

20. It was the ex parte applicant's contention that assuming that the 3rd Respondent is indeed the said applicant, he is content with the vacuum created by the 19th April, 2016 court order that refrained all parties from taking any action as opposed to 5th April, 2016 court Order that allows 5th Respondent to discharge the functions under sections 35 A (5) and 35 I (b) of the *Pharmacy and Poisons Act*, of inspecting and issuing certificate of compliance or otherwise of some of the above manufacturers. In the ex parte applicant's view, there is special relationship between some of the manufacturers, the 4th Respondent and 3rd Respondent's office to the extent that the 3rd Respondent would rather have a vacuum such as the one created by the 19th April, 2016 court order that refrained all parties from taking any action than the 5th April, 2016 court order that allows the 5th respondent to discharge the functions under sections 35 A (5) and 35 1 (b) of the *Pharmacy and Poisons Act*, of inspecting and issuing certificate of compliance or otherwise of some of the above manufactures, obviously, for fear of making more discoveries that are similar to the above, for public good.

21. It was the ex parte applicant's case that the 3rd Respondent shouldn't be bothered with who between the 4th and 5th Respondents carries out the functions under sections 35A (5) and 35 I (b) of the *Pharmacy and Poisons Act*, of inspecting and issuing certificate of compliance or otherwise of some of the above manufacturers, but with whether the same is effectively accompanied as he has the supervisory role over the two institutions that belong to the same Ministry of Health. It was the ex parte applicant's view that the 4th Respondent (Pharmacy and Poisons Board) should have alerted the general public on said dangerous substandard medicines since part of them had

already been dispensed to the public. According to him, the above are serious and dangerous scenarios that this honorable Court should seriously consider, on urgency basis, to allow the 5th Respondent (National Quality Control Laboratory) to at least carry out “Special” inspections of Dawa Pharmaceuticals Ltd, Lab & Allied Pharmaceutical, Sphinx Pharmaceuticals Ltd and Others manufacturing that include thorough investigations through sampling the said medicinal substances and others under production to ensure the approved method of manufacture is being followed for purposes of issuing a report and certificates of compliance to Good manufacturing practices (GMP) as provided for in sections 35 A(5) and 35 1 (b) of the **Pharmacy and Poisons Act**.

22.The ex parte applicant submitted that jurisdiction to vary and or set aside the orders of this Honorable Court is one which is sparingly exercised and the reasons for invoking that jurisdiction must be specified and must be on solid basis. In this respect the ex parte applicant relied on **Judicial Review Handbook**, 3rd Edition by **Michael Fordham** where at pages 360 and 361 it is stated that:

“At the request of a defendant or an interested party, the Court can set aside permission previously granted. However, this is a very restricted power. It was never popular with judges, who required there to be a very clear-cut case before discharging the permission...The jurisdiction to set aside is one which is sparingly exercised and the reason for invoking that jurisdiction in a particular case must be specified....”

23.Based on **R vs. Secretary of State for The Home Department, ex p. Begum (1989) 1 Admin LR 110, 112F, R vs. Crown Prosecution Service ex p. Hogg (1994) 6 Admin LR 778, T81E-782A, R vs. Secretary of State for the Home Department ex p. Chinoy (1992) 4 Admin LR 457, 462 D-F, R vs. Customs & Excise Commissioners, ex p. Eurotunnel Plc [1957] CLC 392, 399 F, R vs. Environment Agency, ex p. Leam [1998] Env LR D1 and Aga Khan Education Service Kenya v Republic Ex-parte Ali Seif & 3 Others (2004) eKLR** for the position that this is a jurisdiction that should be very sparingly exercised; that the whole purpose of the [permission] stage would be vitiated if the grant of [permission] were to be regularly followed by an application to set it aside; that whereas it may very well be that [the claimants] will face great, perhaps insuperable, difficulties when the case is finally heard, this was never a case for an application to set aside [permission]” as such an application is not to be brought merely on the footing that a [defendant] has a very powerful, even overwhelming case.

24.To the ex parte applicant, the most recognized grounds for varying and or setting aside judicial review permission/order include instances of material non -disclosure, concealment of material particulars/documents , misrepresentation and where the application for leave/permission/order granted is an abuse of the process of Court. In this respect the ex parte applicant relied on **In the Matter of an Application by Justus Nyangaya & Others**, High Court of Kenya at Nairobi, Misc. Civil Case No. 1133 of 2002 where it was observed at page 9 thus:

“However the Courts have set aside ex-parte orders obtained in judicial review proceedings following non-disclosure of material facts, concealment of material documents and on misrepresentation.”

25.In this case, however, it was contended that 3rd and 4th Respondents/Applicants had not alleged any of the above grounds to be entitled to the orders sought. To the ex parte applicant, misinterpretation of the Orders issued by this Court on the 5th April, 2016 cannot be the basis for varying or setting aside judicial review orders particularly considering the fact that this Honorable Court is the custodian and interpreter of law and any order issued. To him, nothing would have been easier than the Applicants applying for interpretation of the orders. In any event, there is nothing to show that the ex-parte applicant has misinterpreted the orders issued.

26.However the ex parte applicant was of the view that while granting the orders now in question, the Court did not suspend the operation of sections 35A(5) and 35I(b) of the **Pharmacy & Poisons Act**, hence there is absolutely no confusion as resulted by virtue of the orders granted as alleged both the 3rd and 4th Respondents/Applicants. It was contended that the 3rd and 4th Respondents

had not cited any law that empowers the 4th Respondent to carryout GMP Certification Compliance and that rule 10 that was cited by the 3rd Respondent Circular does not appear in any Gazette Notice which rule is in fact a subject of the Judicial Review proceedings herein bearing in mind that the same is in conflict with the provisions of the main Act as cited. The said rule, it was submitted does not empower the 4th Respondent to issue certificates of compliance to Good Manufacturing Practices as alleged by the 3rd Respondent. Most importantly, the rule does not provide for sampling and testing of medicinal samples under production as envisaged in the prescribed manufacturing method besides the fact that the 4th Respondent does not have laboratory capacity to sample and test. It was his submission that the Claim by the 3rd and 4th Respondents that rule 10 of the ***Pharmacy and Poisons (Registration of drugs) Rules*** empowers the 4th Respondent to issue certificates of compliance to Good Manufacturing Practices was false as the said rule only requires the 4th Respondent to make report to the Board.

27. According to the ex parte Applicant whereas this Court can only vary or set aside judicial review orders under its inherent jurisdiction, both the 3rd and 4th Respondents have not invoked the inherent jurisdiction of the Court and in the circumstances, both the applications as filed are fatally defective and requiring to be struck out forthwith. In support of this position the ex parte applicant cited **In the Matter of an Application by Justus Nyangaya & Others**, (supra) at page 9 where it was observed that:

“However the Courts have set aside ex-parte orders obtained in judicial review proceedings following non-disclosure of material facts, concealment of material documents and on

misrepresentation. To enable it to intervene in these situations the Court has invariable invoked its inherent jurisdiction. See R V LAND REGISTRAR KAJIADO exparte KIRSEK INVESTMENTS”.

28. Based on the preliminary objections raised herein, the ex parte applicant was of the view that the two applications ought to be struck out.

Determinations

29. I have considered the submissions filed on behalf of the parties herein.

30. In my view the issues which were raised as preliminary objections cannot be the basis of terminating the subject applications *in limine*. With respect to nexus, it was held in **Republic vs. Land Disputes Tribunal Court Central Division and Another Ex parte Nzioka [2006] 1 EA 321:**

“Judicial review is about fair treatment and for it to remain relevant now and in the future it must each out to enhance democracy and public morality – it has a glorious role and future and in this role it has a partner in the Constitution and as partners the two must keep almost the same pace. The steps must be made in the actual hearings on merit and the threshold is certainly unsuitable. The court must throw away the procedural chains of the past and Civil Procedure Act and the rules should not apply to judicial review. These matters are not straightforward, simple or as plain as they are sometimes intended to be and a summary approach should only be in the plainest of cases only, to save valuable judicial time, and to avoid hampering public administration with unmeritorious claim and also to prevent public bodies from being harassed by irresponsible applications, to prevent the court’s time being taken up by busybodies and finally to remove uncertainty in which public bodies and authorities might be left as to whether they could safely proceed with administrative action while proceedings for judicial review of it were actually pending even though misconceived...At leave stage the court is being asked to exercise a judicial discretion on material available and it is largely a filter stage while the discretion at the second stage is different.”

31. Apart from that in NBI High Court (Civil Division) Civil Case No 102 of 2012 - **Cheraik**

Management Limited vs. National Social Security Services Fund Board of Trustees & Another I expressed myself, *inter alia*, as follows:

“Ordinarily, a preliminary objection should be based on the presumption that the pleadings are correct. It may also be based on agreed facts. It, however, cannot be entertained where there is a dispute as to facts for example where it is alleged by the defendant and denied by the plaintiff that a condition precedent to the filing of the suit such as the giving of a statutory notice was not complied with, unless the fact of non-giving of the notice is admitted so that the only question remaining for determination is the legal consequence thereof. It may also not be entertained in cases where the Court has discretion whether or not to grant the orders sought for the simple reason that an exercise of judicial discretion depends largely on the facts of each particular case which facts must be established before a Court may exercise the discretion...In this case both parties have adopted the unusual mode of arguing the preliminary objection by filing affidavits in support and in opposition thereof respectively. Accordingly part of the Court’s task would be to determine what are the agreed facts contained therein whether expressly or by legal implication.”

32. In arriving at that decision, I relied on the celebrated case of Mukisa Biscuits Manufacturing Ltd. vs. West End Distributors Ltd. Civil Appeal No. 9 Of 1969 [1969] EA 696. In that case Law, JA was of the following view:

“A preliminary objection consists of a point of law which has been pleaded, or which arises from a clear implication out of pleadings, and which if argued as a preliminary point may dispose of the suit. Examples are an objection to the jurisdiction of the court, or a plea of limitation, or a submission that the parties are bound by the contract giving rise to the suit to refer the dispute to arbitration.”

33. As for Newbold, P:

“A preliminary objection is in the nature of what used to be called a *demurrer*. It raises a pure point of law, which is argued on the assumption that all the facts pleaded are correct. It cannot be raised if any fact has to be ascertained or if what is sought is the exercise of judicial discretion. The improper raising of preliminary objections does nothing but unnecessarily increase costs and, on occasion, confuse the issues, and this improper practice should stop”.

34. I also cited Omondi vs. National Bank of Kenya Ltd & Others [2001] KLR 579; [2001] 1 EA 177 where it was held that:

“The objection as to the legal competence of the Plaintiffs to sue (in their capacity as directors and shareholders of the company under receivership) and the plea of *res judicata* are pure points of law which if determined in the favour of the Respondents would conclude the litigation and they were accordingly well taken as preliminary objections...In determining both points the Court is perfectly at liberty to look at the pleadings and other relevant matter in its records and it is not necessary to file affidavit evidence on those matters...What is forbidden is for counsel to take, and the Court to purport to determine, a point of preliminary objection on contested facts or in the exercise of judicial discretion and therefore the contention that the suit is an abuse of the process of the Court for the reason that the defendant’s costs in an earlier suit have not been paid is not a true point of preliminary objection because to stay or not to stay a suit for such reason is not done *ex debito justitiae* (as of right) but as a matter of judicial discretion.”

35. Dealing with the same issue, Ojwang, J (as he then was) in Oraro vs. Mbaja [2005] 1 KLR 141 expressed himself as follows:

“A preliminary objection consists of a point of law which has been pleaded or which arises

by clear implication out of pleadings, and which if argued as a preliminary point may dispose of the suit. Examples are an objection to the jurisdiction of the court, or a plea of limitation, or a submission that the parties are bound by the contract giving rise to the suit to refer the dispute to arbitration. The first matter relates to increasing practice of raising points, which should be argued in the normal manner, quite improperly by way of preliminary objection. A preliminary objection is in the nature of what used to be a demurrer. It raises a pure point of law, which is argued on the assumption that all facts pleaded by the opposite side are correct. It cannot be raised if any fact is to be ascertained or if what is sought is the exercise of judicial discretion. The improper raising of points by way of preliminary objection does nothing but unnecessarily increase costs and, on occasion confuse issues and this improper practice should stop... The principle is abundantly clear. A “preliminary objection” correctly understood, is now well defined as, and declared to be, a point of law which must not be blurred with factual details liable to be contested and in any event, to be proved through the processes of evidence. Any assertion, which claims to be a preliminary objection, yet it bears factual aspects calling for proof, or seeks to adduce evidence for its authentication, is not, as a matter of legal principle, a true preliminary objection which the court should allow to proceed. Where a court needs to investigate facts, a matter cannot be raised as a preliminary point...Anything that purports to be a preliminary objection must not deal with disputed facts, and it must not itself derive its foundation from factual information which stands to be tested by normal rules of evidence. If the applicant’s instant matter required the affidavit to give it validity before the Court, then it could not be allowed to stand as a preliminary objection clearly out of order and, apart from amounting to a breach of established procedure, it had the unfortunate effect of provoking filing of the respondent’s very detailed “affidavit in reply to an affidavit in support of preliminary objection”, which replying affidavit was expressed to be “under protest”...The applicant’s “notice of preliminary objection to representation” cannot pass muster as a procedurally designed preliminary objection. It is accompanied by affidavit evidence, which means its evidentiary foundations are not agreed and stand to be tested. Secondly, the essential claims in the said preliminary objections are matters of great controversy, as their factual foundations are the subject of dispute.”

36. In my view most of the issues raised in the said preliminary objections were issues which called upon this Court to exercise its discretion. Accordingly, such issues could not, properly, be the subject of preliminary objections.
37. The decision whether or not to grant a stay pursuant to leave is no doubt an exercise of judicial discretion and that discretion like any other judicial discretion must be exercised judiciously. The first issue for consideration by the Court is the circumstances under which the Court may grant an order that the grant of leave do operate as a stay of the proceedings in question until the determination of the application, or until the judge orders otherwise. Order 53 Rule 1(4) of the Civil Procedure Rules provides:

The grant of leave under this rule to apply for an order of prohibition or an order of certiorari shall, if the judge so directs, operate as a stay of the proceedings in question until the determination of the application, or until the judge orders otherwise.

38. It is therefore clear that an order that the leave granted do operate as a stay may only be granted in cases where leave granted is with respect to application for prohibition and certiorari. There is, therefore, no discretion to grant stay under Order 53 where what is sought and granted is only leave to apply for *mandamus*. Accordingly, in **Re: Justus Nyangaya and Social Democratic Party Nairobi HCMA 1132 of 2002** Nyamu, J (as he then was) held that at leave stage it cannot be ordered that leave to apply for a *mandamus* order do operate as stay because logically there can be nothing to stay in respect of the leave for *mandamus* unlike orders of certiorari and prohibition where such leave can if ordered by a Judge operate as stay. In this case, the stay sought is pursuant to the application for leave to apply for an order of certiorari, *mandamus* and prohibition hence it follows that the prayer for stay was competently before the Court. Where, however, the decision sought to be quashed has been implemented leave ought not to operate as a stay. See **George**

Philip M Wekulo vs. The Law Society of Kenya & Another Kakamega HCMISCA No. 29 of 2005.

39. This position arises from the fact that once a decision has been implemented stay is no longer efficacious as there may be nothing remaining to be stayed. It is only in cases where either the decision has not been implemented or where the same is in the course of implementation that stay may be granted. Where, therefore the stay is in respect of the grant of leave to apply for prohibition, it must be emphasized that prohibition by its very nature looks to the future hence where the impugned decision has already been implemented prohibition is not the best remedy to seek. See **Kenya National Examinations Council vs. Republic Ex parte Geoffrey Gathenji Njoroge & Others Civil Appeal No. 266 of 1996 (CAK) [1997] eKLR.**
40. However even where the leave is granted to apply for certiorari and prohibition it was held in **Jared Benson Kangwana Vs. Attorney General Nairobi HCCC No. 446 of 1995** that in an application for leave to apply for judicial review and stay of proceedings the Court has to be careful in what it states lest it touches on the merits of the main application for judicial review and that where the application raises important points deserving determination by way of judicial review it cannot be said to be frivolous. Therefore where the outcome of the judicial review might be in a manner contrary to the conclusion reached by the inferior tribunal, stay of proceedings should be granted as it might lead to an awkward situation.
41. **Maraga, J** (as he then was) in **Taib A. Taib vs. The Minister for Local Government & Others Mombasa HCMISCA. No. 158 of 2006** was of the view that:

“As injunctions are not available against the Government and public officers, stay is a very important aspect of the judicial review jurisdiction... In judicial review applications the Court should always ensure that the *ex parte* applicant’s application is not rendered nugatory by the acts of the Respondent during the pendency of the application and therefore where the order is efficacious the Court should not hesitate to grant it though it must never be forgotten that the stay orders are discretionary and their scope and purpose is limited... The purpose of a stay order in judicial review proceedings is to prevent the decision maker from continuing with the decision making process if the decision has not been made or to suspend the validity and implementation of the decision that has been made and it is not limited to judicial or quasi-judicial proceedings as it encompasses the administrative decision making process being undertaken by a public body such as a local authority or minister and the implementation of the decision of such a body if it has been taken. It is however not appropriate to compel a public body to act... A stay order framed in such a way as to compel the Respondents to reinstate the applicant before hearing the Respondent cannot be granted.”

42. Those then are the principles under which the Courts do exercise their discretion in granting an order for stay. However, it is not in doubt that such an order, if granted *ex parte*, may be set aside at a later stage if the Court finds that the stay ought not to have been issued in the first place or that the change in circumstances no longer warrant the continued existence of the orders of stay. Parties and their counsel are, however, cautioned that the grant of an order of stay ought not to be followed by an application seeking to vacate the same. It is only in cases where the Court is convinced that the conduct of the applicant at the *ex parte* stage when the stay was granted does not justify the grant either by non-disclosure of material facts or misrepresentation of the same or due to subsequent events that the Court will set aside the stay granted. This is due to the fact that Courts do not grant orders of stay as a matter of course and where the Court is in doubt, the Court is now at liberty to direct that the prayer seeking the stay be heard *inter partes* even in cases where the leave has been granted.
43. In this case the *ex parte* applicant’s case is that the 2nd Respondent, the Cabinet Secretary’s action was ultra vires the provisions of the ***Pharmacy and poisons Act***. Sections 35A and 35I of the said Act provides as follows:

35A (1) No person shall manufacture any medicinal substance

unless he has been granted a manufacturing licence by the Board.

(2) Each manufacturing licence shall expire on the 31st

December of every year and the renewal thereof shall be subject to compliance with the conditions prescribed by the Board.

(3) No person shall manufacture any medicinal substance for

sale unless he has applied for and obtained a licence from the Board in respect of each substance intended to be manufactured.

(4) Any person who intends to manufacture a medicinal substance shall make an application in the prescribed form for the licensing of the premises and the application shall be accompanied by the prescribed fee.

(5) The Director of the National Drug Quality Control Laboratory or any member of the Laboratory staff authorized by him shall have power 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.

35I. The Director shall have power—

(a) to develop and administer a data bank on quality assurance on behalf of the Board of management;

(b) to inspect premises and issue certificates of compliance; and

(c) to advise and obtain advice from the Board of management

in regard to any matter within his purview under this Act.

44. A *prima facie* reading of the above provisions would lead one to believe, without making a conclusive or definitive finding, that the Board and the Director while performing their statutory mandates of medicines control complement each other and ought to work hand in hand to ensure that their statutory mandates are achieved for the general welfare of the public. However the provisions clearly evince an intention to create distinctive roles with one body having the regulatory role while the other ensuring compliance. This is however a peremptory view and is not to be taken as the final decision of the Court.

45. What provoked these proceedings however was the circular by the Principal Secretary of Health of 10th March, 2016 by which he directed the Director of National Quality Control Laboratory to stop implementation of the functions under sections 35A and 35I(b) of the said Act.

46. What is therefore in contention is whether rule 10 of the Pharmacy and Poisons (registration of drugs) Rules can supersede the provisions of the Act, a matter which will be determined in due course.

47. In the meantime it is my view that the interests of the public must be protected taking into account the sensitive role played by medicine in the welfare of the society. In my view, pending the determination of the issues raised herein, it is important that the *status quo ante* the said circular be maintained.

48. Having considered the issues raised, herein barring anything else, it is my view that the public interest dictates that there be a smooth and certain manner of determining the quality of medicines being released to the market. As appreciated by **Francis Bennion** in **Statutory Interpretation**, 3rd Edition at page 606:

“it is the basic principle of legal policy that law should serve the public interest. The court... should therefore strive to avoid adopting a construction which is in any way adverse to the public interest”.

49. Further, in **Kenya Anti-Corruption Commission vs. Deepak Chamanlal Kamani and 4 Others, [2014] EKLK** it was held that:

“...a matter of public interest must be a matter in which the whole society has a stake, anything affecting the legal rights or liability of the public at large”.

50. As is appreciated in *Black's Law Dictionary, 9th Edn.* “public interest” is the general welfare of the public that warrants recognition and protection and it is something in which the public as a whole has a stake; especially an interest that justifies governmental regulation. Article 1(1) of the Constitution provides that all sovereign power belongs to the people of Kenya and shall be exercised only in accordance with the Constitution while under Article 1(3)(c) sovereign power under the Constitution is delegated *inter alia* to the Judiciary and independent tribunals. Dealing with a similar provision in **Rwanyarare & Others vs. Attorney General [2003] 2 EA 664**, it was held with respect to Uganda that judicial power is derived from the sovereign people of Uganda and is to be administered in their names. Similarly, it is my view and I so hold that in Kenya under the current Constitutional dispensation judicial power whether exercised by the Court or Independent Tribunals is derived from the sovereign people of Kenya and is to be administered in their name and on their behalf. It follows that to purport to administer judicial power in a manner that is contrary to the expectation of the people of Kenya would be contrary to the said Constitutional provisions. I therefore associate myself with the decision in **Konway vs. Limmer [1968] 1 All ER 874** that there is the public interest that harm shall not be to the nation or public and that there are many cases where the nature of the injury which would or might be done to the Nation or the public service is of so grave a character that no other interest public or private, can be allowed to prevail over it.

51. It is therefore my view and I so hold that in appropriate circumstances, Courts of law and Independent Tribunals are properly entitled pursuant to Article 1 of the Constitution to take into account public or national interest in determining disputes before them where there is a conflict between public interest and private interest by balancing the two and deciding where the scales of justice tilt. Therefore the Court or Tribunals ought to appreciate that in our jurisdiction, the principle of proportionality is now part of our jurisprudence and therefore it is not unreasonable or irrational to take the said principle into account in arriving at a judicial determination.

52. What the Court ought to do when confronted with such circumstances is to consider the twin overriding principles of proportionality and equality of arms which are aimed at placing the parties before the Court on equal footing and see where the scales of justice lie considering the fact that it is the business of the court, so far as possible, to secure that any transitional motions before the Court do not render nugatory the ultimate end of justice. The Court, in exercising its discretion, should therefore always opt for the lower rather than the higher risk of injustice. See **Suleiman vs. Amboseli Resort Limited [2004] 2 KLR 589**.

53. In my view, it is in the wider interest of justice that the 4th and 5th Respondents continue playing their complementary roles in the control of medicines control pending the hearing and determination of these proceedings. I wish to cite the decision of the Court of Appeal in **Nakumatt Holdings Limited vs. Commissioner of Value Added Tax [2011] eKLR** expressed itself with respect to setting aside leave as follows:

“Although leave granted *ex parte* can be set aside on an application, that is a very limited jurisdiction and will obviously be exercised very sparingly and on very clear cut cases unless it be contended that judges of the Superior Court grant leave as a matter of course which is not correct. Unless the case is an obvious one, such as where an order of *certiorari* is being sought and it is clear to the court that the decision sought to be quashed was made more than six months prior to the application coming to court and there is, therefore, no prospects at all of success, the court would discourage practitioners from routinely following the grant of leave with application to set aside. Fortunately such applications are rare and like the Judges in the United Kingdom, the court would also point out that the mere fact that an applicant may in the end have great difficulties in proving his case is no basis for setting aside leave already granted.”

54. In my view the foregoing sentiments apply *mutatis mutandi* to an application for setting aside stay.

55. The main ground upon which the two applications were hinged was that the ex parte applicant herein had misinterpreted the orders issued by the Court herein. If that was the position, it is my view that that does not warrant the setting side or variation of the stay. As was held in **Mary Anne Njuguna vs. Joseph Njuguna Ngae Civil Application No. Nai. 195 of 1997:**

“A judge is not concerned with what litigants may brag or boast as he is only concerned with dispensing justice according to law, and any boasts made by litigants ought not to perturb or even bother a Judge.”

56. However, it is my view that the effect of the order granted herein was that the 5th Respondent would be entitled to carry out its statutory mandate under the parent Act while the Board did the same pending the hearing and determination of these proceedings.

57. Accordingly, I am not satisfied that I ought to vary or set aside the orders of this Court made on 5th April, 2016. In the premises, the applications dated 19th April, 2016 and 21st April, 2016 fail and are dismissed.

58. The costs of the said applications will be borne by the 3rd and 4th Respondents.

59. Orders accordingly.

Dated at Nairobi this 15th day of June 2016

G V ODUNGA

JUDGE

Delivered in the presence of:

Mr. Masika for the Applicant.

Prof Wangai for the 3rd Respondent

Miss Kiarie for PLO Lumumba for the 5th Respondent

Cc Mutisya