



REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA

AT NAIROBI

JUDICIAL REVIEW DIVISION

MISCELLANEOUS CIVIL CAUSE NO. 214 OF 2011

IN THE MATTER OF: AN APPLICATION BY MR RONALD OJUKU (*The Ex parte Applicant*) FOR LEAVE TO APPLY FOR JUDICIAL REVIEW FOR THE ORDERS OF CERTIORARI AND MANDAMUS AGAINST THE REGISTRAR AND CHAIRMAN OF PHARMACY AND POISONS BOARD, THE PERMANENT SECRETARY OF THE MINISTRY OF MEDICAL SERVICES AND THE DIRECTOR OF NATIONAL QUALITY CONTROL LABORATORY (*"The Respondents"*)

IN THE MATTER OF: THE DECISION BY THE 1ST RESPONDENT (REGISTRAR) TO APPOINT AND GAZETTE THE BOARD OF MANAGEMENT OF NATIONAL QUALITY CONTROL LABORATORY IN CONTRAVENTION OF SECTION 35(F) 1 OF PHARMACY AND POISONS ACT (CAP 244) LAWS OF KENYA ON 4TH MARCH, 2011

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

IN THE MATTER OF: THE REPORT ON THE MANAGEMENT SYSTEMS AUDIT OF PHARMACY AND POISONS BOARD (PPB), MARCH 2011 BY EFFICIENCY MONITORING UNIT (EMU)

BETWEEN

MR RONALD OJUKU MOMANYI.....APPLICANT

VERSUS

THE REGISTRAR, PHARMACY AND POISONS BOARD.....1ST RESPONDENT

THE PERMANENT SECRETARY, MEDICAL SERVICES MINISTRY....2ND RESPONDENT

THE CHAIRMAN, PHARMACY AND POISONS BOARD.....3RD RESPONDENT

THE DIRECTOR, NATIONAL QUALITY CONTROL LABORATORY.....4TH RESPONDENT

JUDGEMENT

Introduction

1. By a Notice of Motion dated 20th September, 2011 the *ex parte* applicant herein **Ronald Ojuku Momanyi** seeks the following orders:
 1. **An Order of Certiorari to have the decision of the Registrar of Pharmacy and Poisons Board made on 4th March 2011, in appointing and gazetting the Board of Management of the National Quality Control Laboratory removed into the High Court for the purposes of its being quashed;**
 2. **An Order of Mandamus be issued to compel the 1st, 2nd and 3rd Respondents to issue a public alert notice henceforth and recall the medicines that failed National Quality Control Laboratory tests but were irregularly registered as recommended in the evaluation and Monitoring Units Report (EMU) report and compel the Respondents to abide by the Evaluation and Monitoring Units (EMU) report's recommendation of dissolving the illegal Board of Management of National Quality Control Laboratory (NQCL) and appoint a new Board in accordance with the law.**
 3. **THAT an order of Prohibition do issue against the Board of Management of National Quality Control Laboratory prohibiting the said Board henceforth from carrying on the functions of the Board of Management of National Quality Control Laboratory.**
 4. **That the costs of Application be provided for.**

Applicant's Case

2. The application was supported by a verifying affidavit sworn by the applicant on 30th August, 2011.
3. According to the deponent, as a citizen of the Republic of Kenya he became aware of the health hazards posed by the introduction to the Kenyan market of substandard drugs and medicines which pose a threat to the people of Kenya and that this situation has been occasioned by irregularities perpetuated by various officials in the Ministry of Public Health.
4. He deposed that by a Gazette Notice No. 2064 dated 24th February 2011, and contained in VOL. CX111 – No. 21 of 4th March 2011 the 2nd respondent herein **K.C. Koskei** as the Registrar, Pharmacy and Poisons Board (hereinafter referred to as the Board) in exercise of powers purportedly conferred under Section 35 F(1) of the **Pharmacy Act** Cap 244 Laws of Kenya (hereinafter referred to as the Act) purported to appoint 9 persons to be members of the Board of Management, National Quality Control Laboratory for a period of three (3) years with effect from 4th March 2011. The applicant contended that the purported appointment was done unilaterally and did not follow the procedure provided for under the relevant law and was intended to establish a Board which would implement the devious designs of the officials at the Ministry of Health to which the importation of substandard medicines to the Kenyan market. Following accusations at the Ministry and the Department, the then Permanent Secretary in the Ministry of Health invited an investigation in or about March 2011 from the Evaluation and Monitoring Unit of the Prime Minister's Office (hereinafter referred to as EMU) to investigate and make recommendations and a month or so later in April, the EMU forwarded their report with recommendations among which were that the Registrar of the Board through gazette notices appointed previous and current Board of Members of National Quality Control Laboratory contrary to provisions of Section 35 (F) and recommended for immediate dissolution of the current Board of Members of National Quality Control Laboratory and appointment of a new one in conformity with the Act.
5. It was deposed that the said findings and recommendations by EMU have been ignored by the Minister/Permanent Secretary of Medical Services Ministry and contrary to the rules of the Act, the said Registrar registered medicines that failed National Quality Control Laboratory tests as highlighted in the EMU report.
6. According to the applicant, the registered medicines, which failed National Quality Control

- Laboratory tests are dangerous to the unsuspecting general public, some of which like Penicillin 250 mg is used in the Intensive Care Unit (ICU) in hospitals, and indeed it has been a matter of serious public concern since the patients may die due to use of such medicine.
7. According to the applicant, despite the EMU report findings which were submitted in March 2011, the said Registrar, Minister, Permanent Secretary, Chairman of the Pharmacy and Poisons Board, have not bothered to issue a public notice to the public for caution nor withdraw the said medicines from the market – thus the general public continues to consume the dangerous drug to date and this is despite the fact that an official at National Quality Control informed the PS to ensure National Quality Control Board is appointed legally. Instead the said officer was interdicted by the PS for what was termed “insubordination”.
 8. It is the applicant’s case that the Registrar licences medicines to be imported from companies that failed Good Manufacturing Practices (GMP) inspection thus further exposing the general public to dangerous medicines. Further, the EMU noted numerous financial misappropriations running into millions of shillings that should be recovered by surcharging those involved in the scam. To the applicant, the same Registrar practices nepotism in posting officers to the Board thus ensuring that dangerous medicines easily enter the country through patronage hence the Board has in continued conferment of the law to import substandard drugs which matter has attracted the attention of the National Assembly Sub-committee of Health.
 9. As a result of the mounting pressure from the bad practices in the department, the members of the illegal committee including the Chairperson have recently rendered their resignations from the Board.
 10. It was therefore concluded by the applicant that the continued existence of the committee continues to hazard the public as the Board has failed to implement the recommendations of the EMU report.
 11. There was also a further affidavit sworn by the applicant on 22nd November, 2011.

1st and 3rd Respondents’ Case

12. In response to the application the 1st and 3rd Respondents filed a replying affidavit sworn by **Dr Kipkerich Koskei**, the Registrar and the Secretary of the Board on 26th October, 2011.
13. According to the deponent, the Notice of Motion by the Applicants is fatally defective, incompetent and a total abuse of the law and Order 53 of the **Civil Procedure Rules** and as it thoroughly fails to comply with the mandatory fundamental tenets of Judicial Review.
14. According to him, the Board is a corporate body established under the Act to regulate and oversee Pharmaceutical services in the country and under the Act the Board is also mandated to appoint a Board of Management for National Quality Control Laboratory pursuant to Section 35 F(1) of the Laws of Kenya. To him, the Applicant is not an expert in pharmaceutical products on such matters but a busy body hence cannot claim that the drugs and medicines in the Kenyan market are substandard and pose a threat to the people of Kenya and that the Applicant failed to provide any particulars on this fact; he failed to give any evidence on the damages caused; and there is no connection on this fact. He then proceeded to deny the allegations made out under paragraph 3 of the Supporting Affidavit and the irregularities perpetuated by the officials in the Ministry of Public Health and averred any such irregularities if they exist are not within the premises of the 1st and 3rd Respondents.
15. According to the deponent, on 7th February 2011 the Director of National Quality Control Laboratory vide a letter Ref **No. DNQCL/PPB-11/-2001** informed the Board that the term of the Board of Management, National Quality Control Laboratory (NQCL) had expired and submitted nine (9) nominees for consideration and gazette. Following the vetting of the nominees by the Permanent Secretary (PS) Medical Services Ministry, the 3rd Respondent and the deponent, four (4) nominees were considered for appointment to the Board of Management of National Quality Control Laboratory while the remaining five (5) nominees were rejected based on conflict of interest, diverse skills and expertise, knowledge of good corporate governance having served for more than two (2) terms at the time, gender balance, institutional memory stake holders representation and regional balance. He contended that by powers conferred to the Board under Section **35 F(1)** of the Act in consultation with the Permanent Secretary Medical Services and the

- 3rd Respondent herein, he gazetted new members of the National Quality Control Laboratory Board vide *Kenya Gazette Vol. CXIII-NO 21* which decision was endorsed by the members of the Board.
16. According to the deponent, the EMU report neither indicated anywhere that the National Quality Control Laboratory Board of Management had been appointed contrary to the Provisions of Section 35 F(1) nor that the said Board of Management, National Quality Control Laboratory be dissolved as the same was done above board and the persons appointed were of high moral value and expertise.
 17. In the deponent's view, this being a judicial review process, the Honourable Court has the fundamental jurisdiction to check any excesses emitted by any judicial body while making its decision or implementing its judicial authority. However in this case the Applicant has failed to demonstrate under what basis the 1st and 3rd Respondents acted contrary to the powers vested in them while appointing the National Quality Control Laboratory Board as alleged by the Applicant. To him, EMU is just an organ of the Government which conducts monitoring of the Government Departments on request and therefore its reports are not binding nor final but only persuasive.
 18. It was contended by the deponent that all other issues claiming to do with financial misappropriation and nepotism as raised in the ex-parte Applicants Affidavit are all meant to frustrate the functions of the National Quality Control Laboratory as the matters raised in the EMU report were strictly administrative and that the Honourable Court cannot adjudicate on the same. With respect to the issue of resignation from the Board of Management, National Quality Control Laboratory it was deposed that the same is personal and the Board has no control over the same.
 19. To the deponent, if the Orders sought are granted, operations of the National Quality Control Laboratory shall be paralysed as there will be no legal organ to oversee the operations of the laboratory as its functions are crucial to the analysis of drugs and medicines coming into the Kenyan market.
 20. There was a further replying affidavit sworn by the same deponent on 9th February, 2012.
 21. In the said affidavit it was reiterated that the applicant herein is a busy body is acting solely on malice and/or in bad faith and therefore lacks the locus standi to bring any action against the Board and or its Directors. He emphasized that the NQCL cannot call for a meeting without any agenda, and hence the said meeting held in the month March, 2011 had an agenda in place. To him, the applicant brought an action against the office of the Director, National Quality Control Laboratory, the 4th respondent herein as the officer in charge of the office in question and not in his individual capacity, as such, his transfer to a different department should be treated as an administrative action and not a tacit adjudgement of guilt whatsoever.
 22. To him, the applicant's allegations are based on hearsay, rumours and unfounded information and/or findings should be invited to substantiate the same. He added that the members to the said Board were duly appointed in accordance with the provisions of the law and at no time has the Board acted in contravention of the law while making appointments. He averred that the last meeting by NQCL was held in the month of March, 2011 before this suit was instituted hence all the allegations made are based on hearsay.
 23. According to him, the Director, one **Dr. Hezekiah Chepkwony** had issued two conflicting reports/certificates one indicating that the drugs had passed the tests but sent another one to EMU indicating that the drugs had failed the test hence his being requested to appear before the CDR to explain the discrepancies in the certificates issued.
 24. The deponent reaffirmed the position that the 2nd respondent has no role in the Board of Management and this is crystal clear under Section 35(F)(1) of the Act though is regularly consulted as the accounting officer of the ministry and that the EMU report was an administrative tool intended to improve efficiency whose recommendations have so far been implemented. It was his view that the honourable court has at no particular point in time in his ruling declared and/or insinuated that the 2nd respondent is unfit to hold a public office.
 25. With respect to the issue of import authorization he deposed that the same has been investigated by the Kenya Police, the EMU and the Parliamentary Departmental Committee on Health and he was found to be without blame for the donation and diversion and to him, he has no ties and/or personal connection to Ogra Foundation and as such has not infringed any policy whatsoever. He

averred that the World Health Organization (hereinafter referred to as the WHO) was playing its role perfectly to assist the Board in finding out what was the problem and that upon receipt of the report by WHO, he put up in the local dailies a paid up advert alerting the public to beware of the moulded **Zidolam-N** in the market.

26. The delay in the inauguration of the Board, according to him was caused by the 1st and 3rd respondent is farfetched as indeed the said delay was squarely at the behest of the 4th respondent who kept on engaging the 1st and 3rd respondent in unnecessary correspondence instead of convening the Board.
27. It was emphasised that the members to the said Board were duly appointed in accordance with the provisions of the Act and at no such time has the Board acted in contravention of the law while making appointments.

4th Respondent's Case

28. As for the 4th Respondent, he filed an affidavit in support sworn on 7th October, 2011.
29. According to him, on 19th January, 2011, he vide a letter Ref No. NDQCL/PPB-11/01001 notified the Registrar of the Board to facilitate the appointment of the new Board of Management of the National Quality Control Laboratory and on 7th February 2011, reminded him of the same and forwarded a list of the proposed board members for consideration. On or about 8th March, 2011, he learnt that the new Board of Management of the National Quality Control Laboratory had been gazetted vide Gazette number 2064 of Vol. CXIII – No. 12 dated 4th March, 2011.
30. Subsequently, on 9th March, 2011, he brought the above to the attention of the Permanent Secretary, Ministry of Medical Services detailing to her the 4th Respondent's reservations to the said appointment and on 24th March, 2011, the Permanent Secretary, Ministry of Medical Services vide letter Ref No. EST/29/A/1 VOL IV (19) informed him on the criteria used to appoint the new Board of Management of the National Quality Control Laboratory and on 12th April, 2011, the Permanent Secretary Ministry of Medical Services vide letter Ref No. MED/27/1/1/ (15) inquired from the deponent whether the new Board of Management of the National Quality Control Laboratory had been inaugurated to start its operations.
31. In response thereto, the 4th Respondent on 12th April, 2011, vide letter Ref No. NDQCL/PS-11/04002 informed the Permanent Secretary Ministry of Medical Services that the appointing authority had not formally informed him on the said appointment and vide a letter dated 15th April 2011, copied to the 4th Respondent, the Permanent Secretary Ministry of Medical Services informed the Registrar, to formally communicate to the National Quality Control Laboratory of the said appointment. The communication on the appointment was subsequently communicated to the 4th Respondent on 15th April, 2011, by the Registrar who directed the 4th Respondent to convene a meeting of the new Board of Management for the formal inauguration and the election of the chairman and pursuant to a request by the 4th Respondent, the Registrar provided postal addresses for his action. The 4th Respondent on 6th May, 2011, vide letter Ref No. NDQCL/PPB-11/05001 invited the Registrar of the Board to officiate the inauguration ceremony of the new Board of Management of National Quality Control Laboratory and the new Board was inaugurated on the 12th May, 2011 by the said Registrar. Since its inauguration, the 4th Respondent contended that the new Board since has had about five Board meetings.

Determinations

32. I have considered the application, the various affidavits filed in support of and in opposition to the application as well as the submissions filed.
33. Section 35F of the **Pharmacy and Poisons Act**, Cap 144 Laws of Kenya provides:

(1) There shall be a Board of Management for the Laboratory which shall consist of nine members to be appointed by the Pharmacy and Poisons Board.

(2) A member of the Board of Management appointed under subsection Shall hold office for three years but shall be eligible for reappointment.

(3) A quorum of the Board shall be five members.

(4) The Board of management shall meet not less than four times each calendar year.

5. The Director shall be the secretary of the Board of Management.

6. Subject to this subsection, the Board may regulate its own procedure.

34. It is clear from the foregoing that the Board of Management of the National Quality Control Laboratory is to be appointed by the Pharmacy and Poisons Board. Section 3 of the Act provides for the membership of the Board as follows:

(1) The Minister shall appoint a Board to be known as the Pharmacy and Poisons Board which shall consist of the following persons—

(a) the Director of Medical Services who shall be the Chairman;

(b) the Chief Pharmacist;

(c) the Director of Veterinary Services or a veterinary surgeon nominated by him;

(d) four Pharmacists appointed by the Minister from a panel of names submitted by the Pharmaceutical Society of Kenya of whom—

(i) one shall be from the Civil Service;

(ii) one shall be from the community pharmacy; and

(iii) one from the pharmaceutical industry;

(e) one representative of the Department of Pharmacy of the University of Nairobi nominated by the Faculty Board; and

(f) one pharmaceutical technologist appointed by the Minister from a panel of names submitted by the Kenya Pharmaceutical Society.

35. In this case however, the Registrar deposed that the nominees were vetted by Permanent Secretary (PS) Medical Services Ministry, the 3rd Respondent and the Registrar himself after which the successful nominees were gazetted. It is therefore clear that the people who purported to appoint the members of the Board of Management of the National Quality Control Laboratory had no powers to do so.

36. It was also contended that the said appointment was done unilaterally and did not follow the procedure provided for under the relevant law and was intended to establish a Board which would implement the devious designs of the officials at the Ministry of Health to which the importation of substandard medicines to the Kenyan market. The Registrar was also accused of practising nepotism in posting officers to the Board thus ensuring that dangerous medicines easily enter the country through patronage.

37. The scope of the judicial review remedies of *Certiorari*, *Mandamus* and *Prohibition* was the subject of the Court of Appeal decision in **Kenya National Examinations Council vs. Republic Ex parte Geoffrey Gathenji Njoroge & Others** Civil Appeal No 266 of 1996 in which the said Court held *inter alia* as follows:

““Prohibition looks to the future so that if a tribunal were to announce in advance that it would consider itself not bound by the rules of natural justice the High Court would be

obliged to prohibit it from acting contrary to the rules of natural justice. However, where a decision has been made, whether in excess or lack of jurisdiction or whether in violation of the rules of natural justice, an order of prohibition would not be efficacious against the decision so made. Prohibition cannot quash a decision which has already been made; it can only prevent the making of a contemplated decision...Prohibition is an order from the High Court directed to an inferior tribunal or body which forbids that tribunal or body to continue proceedings therein in excess of its jurisdiction or in contravention of the laws of the land. It lies, not only for excess of jurisdiction or absence of it but also for a departure from the rules of natural justice. It does not, however, lie to correct the course, practice or procedure of an inferior tribunal, or a wrong decision on the merits of the proceedings...The order of *mandamus* is of a most extensive remedial nature, and is, in form, a command issuing from the High Court of Justice, directed to any person, corporation or inferior tribunal, requiring him or them to do some particular thing therein specified which appertains to his or their office and is in the nature of a public duty. Its purpose is to remedy the defects of justice and accordingly it will issue, to the end that justice may be done, in all cases where there is a specific legal right or no specific legal remedy for enforcing that right; and it may issue in cases where, although there is an alternative legal remedy, yet that mode of redress is less convenient, beneficial and effectual. The order must command no more than the party against whom the application is legally bound to perform. Where a general duty is imposed, a *mandamus* cannot require it to be done at once. Where a statute, which imposes a duty, leaves discretion as to the mode of performing the duty in the hands of the party on whom the obligation is laid, a *mandamus* cannot command the duty in question to be carried out in a specific way... These principles mean that an order of *mandamus* compels the performance of a public duty which is imposed on a person or body of persons by a statute and where that person or body of persons has failed to perform the duty to the detriment of a party who has a legal right to expect the duty to be performed. An order of *mandamus* compels the performance of a duty imposed by statute where the person or body on whom the duty is imposed fails or refuses to perform the same but if the complaint is that the duty has been wrongfully performed i.e. that the duty has not been performed according to the law, then *mandamus* is wrong remedy to apply for because, like an order of prohibition, an order of *mandamus* cannot quash what has already been done...Only an order of *certiorari* can quash a decision already made and an order of *certiorari* will issue if the decision is without jurisdiction or in excess of jurisdiction, or where the rules of natural justice are not complied with or for such like reasons. In the present appeal the respondents did not apply for an order of *certiorari* and that is all the court wants to say on that aspect of the matter.”

38. Apart from the issue of the excess exercise of jurisdiction in appointing the members of the Board of Management of the National Quality Control Laboratory, it is my view that the other allegations made by the applicant went to the merits. However judicial review proceedings do not deal with the merits of the decision but by the decision making process. In **Municipal Council of Mombasa vs. Republic & Umoja Consultants Ltd Civil Appeal No. 185 of 2001** the Court of Appeal held:

“Judicial review is concerned with the decision making process, not with the merits of the decision itself: the Court would concern itself with such issues as to whether the decision makers had the jurisdiction, whether the persons affected by the decision were heard before it was made and whether in making the decision the decision maker took into account relevant matters or did take into account irrelevant matters...The court should not act as a Court of Appeal over the decider which would involve going into the merits of the decision itself-such as whether there was or there was not sufficient evidence to support the decision.”

39. Although under section 35F of the Act, the tenure of office of the subject Board ought to have come to an end in March, 2014 which is now past, the said provisions allow for their reappointment. Since their appointment was irregular, an order of *certiorari* ought to and is hereby

- issued quashing their said appointment.
40. With respect to the order of mandamus sought I have not been referred to any particular legal duty placed on the Respondents to issue a public alert notice henceforth and recall the subject medicines. In any case in order for me to make a determination as to whether the subject drugs are substandard, it would require this court to make a determination on merits which is not within the jurisdiction of this Court. Accordingly the order of mandamus does not lie in the circumstances of this case.
41. As I have found that the Respondents acted ultra vires their powers in appointing the said Board, I hereby issue an order prohibiting the subject Board of Management of National Quality Control Laboratory if it is still in the office henceforth from carrying on the functions of the Board of Management of National Quality Control Laboratory.
42. The costs of this application are awarded to the ex parte applicant.

Dated at Nairobi this day 19th day of May 2014

G V ODUNGA

JUDGE

Delivered in the presence of:

Ms Sirai for Mr Momanyi the Applicant

Mr Rono for Mr Naikuni for the 1st and 3rd Respondents

Cc Kevin