



REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA

AT NAIROBI

JUDICIAL REVIEW APPLICATION NO. E043 OF 2021

IN THE MATTER OF AN APPLICATION FOR JUDICIAL REVIEW

ORDERS OF FOR ORDERS OF CERTIORARI AND PROHIBITION

BETWEEN

REPUBLIC.....APPLICANT

VERSUS

THE KENYA MEDICAL LABORATORY

TECHNICIANS AND TECHNOLOGISTS BOARD.....RESPONDENT

AND

PHARMACY AND POISONS BOARD.....1ST INTERESTED PARTY

CABINET SECRETARY, MINISTRY OF HEALTH.....2ND INTERESTED PARTY

THE ATTORNEY GENERAL.....3RD INTERESTED PARTY

EX PARTE APPLICANT:

ASSOCIATION OF MEDICAL LABORATORY

DIAGNOSTICS SUPPLIERS

Suing through its officials

John Karume- Chairman

Paul Wambura- Treasurer

Feroz Nawab - Secretary

RULING NO.2

1. On 29th March 2021, this Court granted the Association of Medical Laboratory Diagnostics Suppliers suing through its officials (hereinafter the *ex parte* Applicant), leave to commence judicial review proceedings with respect to by memos dated 21st December 2020 and 12th March 2021 issued by the Kenya Medical Laboratory Technicians and Technologists Board, the Respondent herein. The Court also directed that prayers 4 and 5 of the substantive Chamber Summons application dated 25th March 2021 that were seeking orders that the said leave operates as a stay, or that in the alternative the *status quo ante* be maintained, be canvassed *inter partes*.

2. The *ex parte* Applicant's application is supported by a supporting affidavit sworn on 25th March 2021 by Isaac Omeke Miencha, the *ex parte* Applicant's Advocate on record, a verifying affidavit sworn on the same date by Feroz Nawab, the *ex parte* Applicant's Secretary, and a Statutory Statement also dated 25th March 2021. The *ex parte* Applicant has since filed a substantive Notice of Motion dated 5th April 2021, and its advocates on record, Naikuni Ngaah and Miencha Advocates, also filed submissions of even date on the issue of stay.

3. The Respondent filed a replying affidavit sworn on 20th April 2021 by Abdulatif Ali, its Registrar. In addition, its advocates on record, Githinji Mwangi Company Advocates, filed submissions dated 21st April 2021 on the issue of stay. The 1st Interested Party on its part filed a replying affidavit sworn on 7th May 2021 by Dr. Ronald Inyangala, its Product Evaluation and Registration Director, while the 2nd Interested Party filed a replying affidavit deposed to on 10th May 2021 by Dr. Julius Ogato, the Head of Department in Health Systems Strengthening, Chimau Judith, a Principal State Counsel in the Attorney General's Office filed submissions on behalf of the Interested Parties.

The Respective Cases

The ex parte Applicant's Case

4. The *ex parte* Applicant case is that the impugned memos issued by the Respondent on 21st December 2020 and 12th March 2021 has made production of evidence that the test/reagents and equipment used by laboratories have been validated by the Respondent a pre-requisite to licensing of laboratory facilities. Further, that the Respondent requires all suppliers, vendors, distributors of test kits/reagents and equipment used for clinical tests to register with it.

5. It is the *ex parte* Applicant's case that its members, who comprise suppliers, vendors and distributors, are currently not licensed by the Respondent, and that section 5(2)(d) as read together with section 21 of the Medical Laboratory Technicians & Technologists Act provide that the Respondent shall license medical laboratory technicians and technologists. Further, that the 1st Interested Party has over the years exercised the role contemplated in the impugned memos pursuant to Legal Notice 192 of 2010 and Gazette Notice No. 1879 dated 21st March 2014, and as clarified in correspondence by the Interested Parties. Therefore, that the *ex parte* Applicant is already being subjected to regulation in relation to the products that are the subject of the said memos. Lastly, that Legal Notice No. 113 of 2011 (Medical Laboratory (Equipment and Reagents Validation) Regulations, 2011) in which has been relied on by the Respondent is *ultra vires* the provisions of the Medical Laboratory Technicians & Technologists Act and was not subjected to public participation.

6. The decisions in the cases of **R vs Cabinet Secretary for Transport & Infrastructure & 5 Others Ex- Parte Kenya County Bus Association (Thro' Paul G. Muthumbi Chairman, Samuel Njuguna Secretary, Joseph Kimiri Treasurer & 8 Others); Nairobi City County Government vs Chief of Defence Forces, Kenya Defence Forces & 2 others [2016] eKLR; R (H) vs. Ashworth Hospital Authority [2003] WLR 127; and R vs National Hospital Insurance Fund Management Ex Parte Patanisho Maternity & Nursing Home [2019] eKLR**, were cited for the circumstances under which leave granted by a Court can operate as a stay, and for the submission that the implementation of the memos dated 20th December 2020 and 12th March 2021 have not been completed as the process of licensing medical laboratory facilities through the implementation of Legal Notice No. 113 of 2011 is continuous.

The Respondent's Case

7. The Respondent's case on the other hand is that under the Medical laboratory Technicians and Technologists Act, it is the sole regulatory body in Kenya with legal mandate to exercise general control and supervision over the training, business, practice, and employment of the medical laboratory technicians and technologists. Further, that its role as contemplated under Section 5 of Act also includes teaching, training, mentorship, clinical research, manufacture of invitro diagnostics (IVDs), buying, selling, installation, care and maintenance of IVDs and general advisory on all matters relating to the same.

8. In addition, that pursuant to the provisions of section 21 of the Act, the Respondent is mandated to issue practising certificate and annual licenses authorizing the Medical Laboratory Technicians and Technologists named therein to engage in private practice, and the provisions of Section 25 of the Act mandates the Respondent to provide for the equipment and reagents to be provided in all medical laboratories in regulations, which gave rise to Legal Notice no. 113 of 2011.

9. According to the Respondent, stay orders will cripple the performance of its statutory functions, and that ten (10) years have elapsed since enactment of Legal Notice No.113 of 2011 and members of the Applicant in recognition of the mandate of the respondent have applied and been registered by the respondent, and the validation of products they deal in is ongoing. The Respondent annexed a copy of the list of the *ex parte* Applicant's members registered with Respondent since 2011 and of a validation report as at 10th April, 2021. Therefore, that suppliers of invitro diagnostics that have complied and continue to comply with L.N. No 113 OF 2011, and the 1st Interested Party is interfering with its mandate.

10. Lastly, that given the emerging numerous cases of false laboratory test results relating to the use of invitro diagnostics that have not been validated by the Respondent, it is necessary to enhance regulatory vigilance to achieve the envisioned standards of healthcare in Article 43 of the Constitution. Therefore, that if this application is granted it will be used to advance commercial interests which do not override the interests of the larger Kenyan public. In addition, that the *ex parte* Applicant's application will not be rendered nugatory as any losses incurred are financial in nature and quantifiable, and can be remedied by way of damages.

11. The Respondent relied on the decision in case of **James Mburu Gitau t/a Jambo Merchant vs Sub county Public Health Officer Kiambu County (2013) e KLR** for the guiding principles in granting an order for leave to operate as stay, and submitted that the decision whether the said memos were issued wrongly or rightfully issued should be canvassed at the full hearing of the motion and not at this stage, and that an order of stay as sought by the Applicants herein the stay will operate as a mandatory injunction compelling the Respondent to allow the *ex parte* Applicant to supply to laboratories unvalidated invitro diagnostics .

12. It was additionally submitted that the grant of a stay would expose the members of the public to unregulated medical laboratory services and loss of lives. The decisions in **Karua vs Radio Africa Limited T/A Kiss FM Station and Others, (2006) 2 KLR 375, Republic vs The Kenya Medical Laboratory Technicians & Technologists Board, ex parte Valley Hospital Ltd, Judicial Review Application No. 22 of 2015** and **Kings Medical College Ltd vs Kenya Medical Laboratory Technicians and Technologists Board And 2 Others, Constitutional Petition No. 8 of 2017** were cited for the position that in giving effect to rights, the courts must balance fundamental rights of individual against the public interest.

The Interested Parties' Case

13. The Interested Parties position is that the Pharmacy and Poisons Board, which is the 1st Interested Party herein, is responsible for the regulation of health products and technologies, as stipulated under section 3B of the Pharmacy and Poisons Act. Further, that health products are defined under section 2 of the said Act to include medicinal substances, medical devices and diagnostics. In addition, that Parliament, through the Health Laws Amendment Act, March 2019 identified Pharmacy and Poisons Board as the single regulatory body as envisaged under section 62 of the Health Act, 2017, and section 109 of the Health Act, 2017 outlaws any sections of the existing health laws that may be in conflict with any sections of the Health Act, 2017.

14. According to the Interested Parties, the Health Act No. 21 of 2017 under Section 60 (2)(c) recognizes the Respondent as a professional regulatory body in line with the statute for its establishment. However, that the Respondent purports to be the regulator for reagents, medical devices and diagnostics including in-vitro diagnostics, which is strictly within the purview of the 1st Interested Party, and has continuously led to confusion among stakeholders as to the proper body from which to obtain marketing authorization.

15. Furthermore, that the Respondent's Chairman, in exercise of the powers conferred by section 25 of the Medical Laboratory Technicians and Technologists Act, enacted the Medical Laboratory (Equipment and Reagents Validation) Regulations of 2011, which were intended to regulate private practice and business of the laboratory technicians, but were extrapolated to include product regulation.

The Determination

16. I have considered the arguments by the parties, and I am guided by the exposition on the purpose of a stay in **R (H). vs Ashworth Special Hospital Authority (2003) 1 WLR 127**, where it was held that such a stay halts or suspends proceedings that are challenged by a claim for judicial review, and the purpose of a stay is to preserve the *status quo* pending the final determination of the claim for judicial review, and to ensure that a party who is eventually successful in his or her challenge is not denied the full benefit of the success.

17. The circumstances under which a Court may grant a direction that the grant of leave do operate as a stay of proceedings or of a decision, and the factors to be taken into account by the Courts in this regard were laid down in the said decision, and in various decisions by Kenyan Courts. It has in this regard been held that were the action or decision is yet to be implemented, a stay order can normally be granted in such circumstances. Where the action or decision is implemented, then the Court needs to consider the completeness or continuing nature of such implementation. If it is a continuing nature, then it is still possible to suspend the implementation.

18. These positions were also explained in the decisions in **Taib A. Taib vs. The Minister for Local Government & Others Mombasa HCMISCA. No. 158 of 2006, Jared Benson Kangwana vs. Attorney General, Nairobi HCCC No. 446 of 1995. Republic vs Cabinet Secretary for Transport & Infrastructure & 4 Others ex parte Kenya Country Bus Owners Association and 8 Others. (2014) e KLR** and **James Opiyo Wandayi vs Kenya National Assembly & 2 Others, (2016) eKLR.**

19. In the present application, the status of implementation of the subject matter of the impugned memos is disputed, and while the *ex parte* Applicant contends that it has all along been regulated by the 1st Interested Party, the Respondent contends that it has started regulating members of the *ex parte* Applicant. I note in this respect that while the Respondent brought evidence of actions undertaken in the licensing of the *ex parte* Applicant's members, the *ex parte* Applicant did not bring any evidence of registration of its members by the 1st Interested Party. It is also apparent that the contestation as regards the current status is as regards which body is regulating the medical devices and reagents used by the *ex parte* Applicant's members.

20. As the subject matter of the impugned memos issued by the Respondent is of a continuing nature, it is amenable to stay. However, in addition to the status of implementation of a decision, a number of other principles have also been held to affect the exercise of a Court's discretion to grant a stay, particularly in cases where the stay will affect third parties and the general public. These principles include balancing the interests of an applicant with the wider public interest.

21. This Court considered the element of public interest in an application for stay in the case of **Republic vs Kenya Airports Authority & another Exparte Irene Elizabeth Wanjiku Kisangi; Abel Gogo & another (Interested Parties) [2019] eKLR** and cited the case of **R vs Capital Markets Authority ex parte Joseph Mumo Kivai & Another.** where Majanja J held as follows:

“...judicial review proceedings are public law proceedings for vindication of private rights, and for this reason public interest is a relevant consideration in the granting of stay orders. There is thus need to preserve the current *status quo* until the legality or otherwise of the 1st Respondent's proceedings and decision is established.”

22. This element of public interest was also the subject of the decision in **R (H) vs Ashworth Special Hospital Authority (supra)**, where Dyson L.J held;

“Where there is a public interest element involved, the Court strikes a balance between the rights of an individual and the public interest, and in striking that balance, the court should usually refuse to grant a stay unless satisfied that there is a strong, and not merely an arguable, case that a tribunal's decision was unlawful.”

23. This was also the position in the case of **Re Bivac International SA (Bureau Veritas) (2005) 2 EA 42**, wherein Justice Nyamu (as he then was) cited the decision in **R VS Monopolies and Mergers Commission ex parte Argyll Group PLC (1986) 1 WLR 763** (as he then was) in that the Court can refuse to order that leave granted for orders of judicial review does operate as a stay where such a stay would violate the needs of good administration.

24. In the instant application, the licencing of the *ex parte* Applicant's members who are laboratory technicians and technologists, and the regulation of medical devices and reagents used by the *ex parte* Applicant's members, is a matter of public interest, as it will affect the health and lives of patients who are the users of the regulated services. Therefore, while the Respondent's decision is likely to affect the *ex parte* Applicant's members' interests, this is a case where both the due performance of the Respondent's and Interested Parties' statutory duties, and the risk that would result to both the Respondent, Interested Parties and public if the *ex parte* Applicant's members activities are not regulated, justifies continued regulation of *ex parte* Applicant's members.

25. The only issue that this Court needed to clarify was the current circumstances as to which regulator, as between the Respondent and 1st Interested Party, is currently involved in the said regulation. From the evidence provided, it appears that the current status is that the Respondent is currently involved in the licensing of laboratory technicians including validation of their medical kits, equipment and reagents, while the 1st Interested Party has also been regulating the said medical kits, equipment and reagents.

The Disposition

26. In the premises, I hereby make the following orders:

I. Prayers 4 and 5 of the *ex parte* Applicant's Chamber Summons application dated 25th March 2021, are dispensed with in the terms of the following orders as regards the *status quo* that shall be maintained by all the parties herein, pending the hearing and determination of the *ex parte* Applicant's substantive Notice of Motion, or until further orders of the Court:

(a) The members of the *ex parte* Applicant who are laboratory technicians and technologists shall continue to be licensed by the Respondent, subject to a suspension of the directive and requirement in the Respondent's Memos dated 21st December 2020 and 12th March 2021 requiring kits/reagents and equipment used for clinical lab tests to be validated by the Respondent.

(b) The kits/reagents and equipment used for clinical lab tests, and by the laboratory technicians and technologists, and all suppliers, vendors and distributors thereof, shall continue to be regulated by the 1st Interested Party.

II. The costs of the *ex parte* Applicant's Chamber Summons application dated 25th March 2021 shall be in the cause

27. Orders accordingly.

DATED AND SIGNED AT NAIROBI THIS 7TH DAY OF JUNE 2021

P. NYAMWEYA

JUDGE

DELIVERED AT NAIROBI THIS 7TH DAY OF JUNE 2021

J. NGAAH

JUDGE