



No.251

REPUBLIC OF KENYA

IIN THE HIGH COURT OF KENYA AT KISII

MISCELANEOUS CIVIL APPLICATION NO. 82 OF 2011

IN THE MATTER OF AN APPLICATION BY DR. ANIL TAILOR, DR. SOLOMON OMACHE, DR. HEZRON MANDUKU, DR. PETER N. OMBOGA, AND KENYA ASSOCIATION OF PRIVATE HOSPITALS – KISII CHAPTER, FOR JUDICIAL REVIEW (*CERTIORARI & PROHIBITION*)

AND

IN THE MATTER OF: THE MEDICAL PRACTITIONERS AND DENTISTS ACT, CAP. 253

AND

IN THE MATTER OF THE KENYA MEDICAL LABORATORY, TECHNICIANS AND TECHNOLOGISTS ACT NO. 10 OF 1999

AND

IN THE MATTER OF: THE KENYA MEDICAL LABORATORY, TECHNICIANS AND TECHNOLOGISTS BOARD

AND

IN THE MATTER OF: REGISTRATION AND LICENSING OF PRIVATE CLINICAL LABORATORIES

REPUBLIC

AND

KENYA MEDICAL LABORATORY TECHNICIANS

AND TECHNOLOGISTS BOARD..... RESPONDENT

THE MINISTER FOR MEDICAL SERVICES

THE DIRECTOR OF MEDICAL SERVICES.....INTERESTED PARTIES

## EX-PARTE

DR. ANIL TAILOR .....	1 <sup>ST</sup> APPLICANT
DR. SOLOMON OMACHE .....	2 <sup>ND</sup> APPLICANT
DR. HEZRON MANDUKU .....	3 <sup>RD</sup> APPLICANT
DR. PETER N. OMBOGA .....	4 <sup>TH</sup> APPLICANT
KENYA ASSOCIATION OF PRIVATE HOSPITALS	
(KISII CHAPTER) .....	5 <sup>TH</sup> APPLICANT

## JUDGMENT

1. The Applicants in this case are proprietors of various private hospitals and clinical laboratories within Kisii and Nyamira Counties. The 1<sup>st</sup> to 4<sup>th</sup> applicants are qualified and registered medical practitioners under the **Medical Practitioners and Dentists Act (Cap.253)** Laws of Kenya, and, are also licensed to carry out private medical practice.
2. The 1<sup>st</sup> applicant, **Dr. Anil Tailor** is the proprietor of RAM hospital. The 2<sup>nd</sup> applicant, **Dr. Solomon Omache** is associated with Bosongo Medical Centre, while the 3<sup>rd</sup> applicant, **Dr. Hezron Manduku** and the 4<sup>th</sup> applicant, **Dr. Peter N. Omboga** are associated with Hema Hospital and Nyamira Maternity and Nursing Home respectively. The 5<sup>th</sup> applicant is an association of private medical practitioners and/or owners of private hospitals and represents the rights and interests of member private hospital owners within the two counties.
3. The Respondent is a Board established under **Section 3** of the **Kenya Medical Laboratory Technicians and Technologist Act No. 10 of 1999** (hereinafter **Act No. 10 of 1999**) as a body corporate with perpetual succession capable of suing and being sued. The 1<sup>st</sup> and 2<sup>nd</sup> interested Parties are the Minister and Director for Medical Services respectively; and, who under the organization of Government, are responsible for medical services and the attendant regulatory oversight of the sector.
4. On diverse dates in the month of August 2011, the Kenya Medical Laboratory Technicians and Technologists Board, carried out inspection of medical laboratories within Kisii and Nyamira Counties and issued notices for specified measures against those hospital laboratories which did not meet the quality standards set under the **Medical Laboratory Technicians and Technologists Act 1999**. Specifically, the Respondent inspected the clinical laboratory at RAM hospital in Kisii on 23<sup>rd</sup> August 2011 and ordered it to take corrective measures within 30 days failing which the Respondent would commence criminal prosecution against the hospital. On 31<sup>st</sup> August 2011 a similar inspection and notice was issued against Hema Hospital while a notice of immediate closure was issued to Bosongo Medical Centre.
5. The Applicants were aggrieved by the Respondent's actions and moved to this court seeking leave to commence judicial review proceedings against the Respondent. They prayed that such leave do operate as a stay of the decision of the respondent to close the hospitals' medical laboratories. The motion was supported by a Statement of Judicial Review dated 12<sup>th</sup> September 2011 and verified by the Affidavit of **Dr. Solomon Omache**, the 2<sup>nd</sup> Applicant, sworn on the same date on behalf of all the Applicants.
6. Leave was granted by **Makhandia J.**(as he then was) on 20<sup>th</sup> September, 2011 who directed however that the issue of stay be heard *inter partes*. The prayer for stay was subsequently canvassed before me by the parties. A Ruling was delivered on 3<sup>rd</sup> February 2012 allowing the stay pending the hearing and determination of the application.

7. In the meantime and pursuant to the leave granted, the Applicants filed the substantive motion dated 26<sup>th</sup> September 2011 seeking the following specific reliefs:-
- i. *Order of judicial review in the nature of certiorari to quash the decision of the Respondent purporting to close the 2<sup>nd</sup> Applicant's private hospital without requisite mandate, authority and jurisdiction and without regard to the due process of the law.*
    - (ii) *Order of judicial review in the nature of certiorari to quash the notice of intention to institute legal charges against the 3<sup>rd</sup> Applicant for non-registration of the Private Clinical Laboratory under the provisions of Act No. 10 of 1999.*
    - (iii) *Order of judicial review in the nature of prohibition to prohibit the Respondent from enforcing and/or implementing the purported closure and attendant notices issued in respect of the Applicants' hospitals to close the hospital and/or institute legal proceedings against the Applicants for non-registration under the provisions of Act No. 10 of 1999.*
    - (iv) *Order of judicial review in the nature of prohibition to prohibit the Respondent from generally purporting to register and/or license the Applicants' private laboratories under Act No. 10 of 1999.*
  - ii. *Any other orders of the court.*
  - iii. *Costs of the Application.*
8. The parties consented to canvass the application through written submissions which they subsequently highlighted. From my reading of the Applicants' pleadings and submissions, it is apparent that the Applicants are aggrieved by the decisions of the Respondent mainly because, in the Applicants' view the respondent has exercised powers *ultra vires* its mandate.
9. The Applicants' case as set out in their statement of facts and elaborated in the submissions of their learned counsel **Mr. Oguttu**, is that the Respondent lacks the power to register or regulate private clinical laboratories, and contend that such power is in fact solely vested in the **Medical Practitioners and Dentists Board** established under the **Medical Practitioners and Dentists Act (Cap. 253 Laws of Kenya)**. The Applicants further state that as a result of the actions of the Respondent, they are exposed to arbitrary treatment and double jeopardy through regulation by two bodies.
10. It is the Applicants' contention that the Respondent has not only usurped the powers of the **Medical Practitioners and Dentists Board (hereinafter Medical Practitioners Board)** but acted *ultra vires* its mandate. They further contend that the Respondent flouted the rules of natural justice by failing to accord them an opportunity to be heard before the punitive decision and actions were reached.
11. The Respondent on the other hand argues that it has the jurisdiction to issue licences and generally regulate all medical laboratory technicians and technologists and to enforce quality standards in all medical laboratories wherever situated. It insists that private hospital laboratories are not exempted from regulation by the Board.
12. In the replying affidavit sworn by one **Michael Abala Wanga** its Executive Officer, the Respondent avers that it draws its mandate from **Section 5** and **Section 40 (g)** of the **Medical Laboratory Technicians and Technologists Act, (Act No. 10 of 1999)** which law supersedes the Rules made under the **Medical Practitioners and Dentists Board Act** under which the Applicants claim to have been registered. In submissions for the Respondent, learned counsel **Mr. Mongera** stated that the notices in question were specifically in respect of laboratories and not hospitals.
13. The Minister of Medical Services and the Director of Medical Services who are named as interested parties in this application did not respond to the application and have not participated.
14. Before delving into the substance of the application however, it is important for the court to

appreciate its judicial review jurisdiction. **Halsbury's Laws of England, 4<sup>th</sup> edition (2001 Reissue Vo. 1 1 pg. 116)** describes judicial review as the supervisory jurisdiction of the Supreme Court over decisions of inferior courts, tribunals and other bodies or persons who carry out quasi-judicial functions or are charged with the performance of public acts and duties. Such jurisdiction is delimited to interrogating the decision making process for jurisdiction, and procedural fairness. It is not concerned with reviewing the merits of the decision.

15. The Court of Appeal in **Municipal Council of Mombasa –vs- Republic Ex parte Umoja Consultants Ltd, Civil Appeal No. 185 of 2001**, considered the scope of judicial review in the following terms:-

*“as the court has repeatedly said judicial review is concerned with the decision making process, not with the merits of the decision. ... the court would only be concerned with the process leading to the making of the decision. How was the decision arrived at? Did those who made the decision have the power i.e jurisdiction to make it? Were the persons affected by the decision heard before it was made? In making the decision did the decision maker take into account relevant matters or did he take into account irrelevant matters? These are the questions a court having a matter by way of judicial review is concerned with, and such court is not entitled to act as a court of appeal over the decider, (for) acting as an appeal court over the decider would involve going into the merits of the decision itself such as whether there was or was not sufficient evidence to support the decision and that, as we have said, it is not the province of judicial review”.*

16. In the present application, the applicants are questioning the actions of the Kenya Medical Laboratory Technicians and Technologists Board which is a public body charged with a public duty. It is therefore not in question that its decisions and actions are amenable to judicial review. See **National Joint Council for the Craft of Dental Technicians (Disputes Committees ex parte Meat) 1953 1 ALL ER 327.**

17. Having considered the pleadings and submissions before me, as well as the authorities cited, I consider the following to be the issues for my determination:-

- i. Whether the Respondent in issuing the closure notice and notices of compliance to the Applicants acted *ultra vires* its mandate.
- ii. Whether the power to register, license and regulate the business and practice of private medical laboratories vests in the Medical Practitioners and Dentists' Board or the Medical Laboratory Technicians and Technologists Board or concurrently in both Boards
- iii. Whether due process was followed in issuing the notices of compliance and closure.
- iv. whether the applicants are entitled to the judicial review orders sought.

(i) Whether the Respondents in issuing notices of compliance and closure of private medical laboratories acted *ultra vires* its mandate.

18. It is the clear submission of the Applicants through their counsel **Mr. Oguttu** that the mandate to regulate private medical laboratories vests in the Medical Practitioners and Dentists Board established under the **Medical Practitioners and Dentists Act (Cap 253 Laws of Kenya)**. They maintain that being medical practitioners, they have already been duly registered and their medical laboratory practice sanctioned by the said Board; and, that therefore any further regulation by another body would expose them to double jeopardy. They rely on Part VII of the **Medical Practitioners and Dentists (Private Medical Institutions) Rules**. They are clear in their submission that being doctors they cannot be regulated by laboratory technicians and technologists whom they consider their juniors and that **Act No. 10 of 1999** has not vested in the respondent the power to register, license and regulate private clinical laboratories.

19. The respondent on the other hand contends that it has the jurisdiction to regulate all medical

laboratory technicians and technologists and to enforce quality standards in all medical laboratories wherever situated. In submissions for the respondent, **Mr. Mongera** urged the court to draw the distinction between the medical laboratories and the hospitals as the regulatory notices issued by the respondent were in respect of the clinical laboratories and not hospitals as contended by the applicants.

21. The application must turn on the application and interpretation of two Acts of Parliament namely **Act No. 10 of 1999** and **Cap.253** which create the Medical Laboratory Technicians and Technologists Board; and; the Medical Practitioners and Dentists Board respectively; and, their respective mandates in the regulation of medical laboratories and the professionals that man such laboratories. The question to be addressed is the content of the regulation of medical laboratories which body bears the requisite mandate to undertake such regulation. Needless to state, the question would not have been before this court if the Ministry responsible for both bodies had ensured adequate legislative and administrative guidance was brought to bear on the two Boards which seemingly have an overlapping oversight in the medical sector with respect to medical and clinical laboratories.

22. **Article 159(2) of the Constitution** binds the courts and tribunals when exercising judicial authority to protect and promote the purposes and principles of the Constitution. The import of Article 10 (i) is that a judicial officer is expected to uphold national values and principles of governance when interpreting the law. The national values and principles are enunciated as including human dignity, equity, social justice, inclusiveness, equality, human rights, non-discrimination and protection of the marginalized.

23. Although not argued on a constitutional pedestal, I am acutely aware that the matters before me touch on two key constitutional rights. One is the right to the highest attainable standard of health care services (**Article 43 (i) (a)**) and the other the right to consumer protection including the right to goods and services of reasonable quality (**Article 46 (i) (a)**). The purpose of the regulation under scrutiny in the present case is undoubtedly to protect the public from sub-standard medical or health services that would negate their right to health espoused in the Constitution. The court is therefore duty bound to interpret the law in a manner that upholds the constitutional rights aforesaid.

24. A further consideration to be borne in mind when interpreting the law is the public interest. As per Lord Denning, 'this is the most weighty consideration' (**See Wallerstein V. Moir(1974) 1 WLR 273**). The public interest consideration has aptly been expounded by **Francois Bennion in Statutory Interpretation 3<sup>rd</sup> Edition** at **page 606**, in the following terms:-

*“ it is the basic principles of legal policy that law should serve the public interest. The court when considering, in relation to the facts of the instant case, which of the opposing constructions of the enactment would give effect to the legislative intention, should presume that the legislator intended to observe this principle. It should therefore strive to avoid adopting a construction which is in any way adverse to the public interest.”* To understand the scope of the mandate of the Medical Laboratory Technicians and Technologists Board, I have looked at the Act and the regulations made thereunder beyond what was cited to me by the parties. The preamble to **Act No. 10 of 1999** states:- *“An Act of Parliament to provide for the training, registration and licensing of Medical Laboratory Technicians and Technologists, to provide for the establishment, powers and functions of the Kenya Medical Laboratory Technicians and Technologists Board and for connected purposes”* The purview of the operation of the Act would from this preamble appear to be laboratory technicians and technologists on the one hand and the operation of the Board on the other.

25. The Board is established under **Section 3**. Its function under **Section 5(1)** is to “exercise general supervision and control over the training, business, practice and employment of laboratory technicians and technologists in Kenya and to advise the

- Government of Kenya in relation to all aspects thereof.” **Section 5(i) (d) & (e)** specifically mandate the Board to “licence and regulate the business and practice of registered laboratory technicians and technologists” and to “regulate the professional conduct of registered laboratory technicians and technologists; and, to take such disciplinary measures as may be appropriate to maintain proper professional standards.”
26. From a cursory reading of **Section 5(1)** one would readily agree with the Applicants’ submission that these provisions point to regulation of personnel namely, the laboratory technicians and technologists; and, focus more on their training, professional qualifications, and professional conduct; and that the same provisions do not give the Board the jurisdiction to regulate private laboratories.
27. However, to correctly interpret the Board’s mandate as set out in **Section 5(1)** one needs to break down the key components of the regulation envisaged. The primary object of the Act is the training, registration and licensing of medical laboratory technicians and technologists. The focus in this mandate therefore suggests a power conferred on the Board to set standards for training, qualification and entry into the profession and practice of laboratory technology for both the laboratory technicians and technologists. The training mandate of the Board is clearly elaborated in **Section 5(2)**. This interpretation and understanding is common ground to the Applicants and the Respondent.
28. The other element of regulation which appears to go beyond individual technicians and technologists is the aspect of ‘business’ ‘practice’ and ‘employment’. Under **Section 5(2) (d)** the Board “shall licence and regulate the business and practice of registered laboratory technicians and technologists”. “Business,’ ‘practice’ and ‘employment’ are not defined in the Act and I will therefore consider their Dictionary definitions, as well as common parlance. **Black’s Law Dictionary 9<sup>th</sup> Edition**, Pg 226 defines business as ‘1.a commercial enterprise carried on for profit, a particular occupation or employment habitually engaged in for livelihood or gain or simply Commercial transactions’ The **Concise Oxford English Dictionary 11<sup>th</sup> Edition** defines business as: “ a person’s regular occupation or trade. Work to be done or matters to be attended to; 2. A person’s concern. 3. Commercial activity – a commercial organization. It also defines “Practice” as “The practicing of a profession – the business or premises of a doctor or lawyer” From these definitions, it is apparent that medical laboratory technology may be practiced as a career and may also provide a business opportunity for a qualified entrepreneur.
29. Following this, the Act has made extensive provisions for regulation. In the first instance for one to practice he must be registered under the Act. **Section 19** makes registration mandatory by providing that “No person shall act as a laboratory technician or technologist in any health institution in Kenya unless such person is registered under the Act”. It is the duty of the Registrar to maintain a register of all medical laboratory technicians and technologists.
30. Further **sub section (3) of Section 19** prohibits any one in charge of a health institution or any medical laboratory in Kenya from employing a person as a laboratory technician or technologist who is not registered under the Act. **Part IV Section 29** of the Act makes extensive provision for the regulation of laboratory technicians and technologists who engage in private practice .
31. **Section 20, (2) (b)** recognizes that qualified laboratory technicians and technologist can either engage in private practice or be employed by the public service or by private medical facilities. Again although it did not emerge as an issue in this application, it is to be taken for granted that the Applicants have in their employ medical laboratory technicians or technologist whom, by virtue of Section 19 (1) & (3) aforesated must be registered and are therefore subject to regulation by the Board.
32. It would follow therefore that the Board while in exercise of its regulatory mandate under Section 19 would of necessity access private clinical laboratories for the purposes of regulating the

- medical laboratory technicians or technologists who work as such therein. As per the provisions of the Act, they must have requisite training, qualification, registration and must uphold professional conduct and standards set by the Board. And, as will be apparent later on in this Ruling, only use validated medical laboratory reagents and equipment.
33. From these provisions, it is my understanding, that laboratory technicians and technologists are subject to the regulatory authority of the Board wherever they work or practice their profession. Indeed I have found nothing in the submissions of the Applicants to suggest that the laboratory technicians and technologists in their employ in the private laboratories should not be subject to the elaborate regulatory framework under **Act No. 10 of 1999**.
34. **Section 25 and Section 40 of Act No. 10 of 1999** gives the Board the power to make regulations for the better carrying out of the provisions of the Act. Section 25(2) provides for the making of regulations for the equipment and reagents to be provided in private medical laboratories; the services to be rendered by laboratory technicians and technologists in private practice; and, the employment of laboratory technicians and technologist in private medical laboratories.
35. **Section 40** on the other hand gives the Board the power to make regulations respecting *inter alia* the standards and conditions of professional practice of registered laboratory technicians and technologists, forms and fees, and the inspection of medical laboratories. Of relevance to this application are Regulations made pursuant to **Section 40** respecting the registration of medical laboratories and their inspection. A read through of the Kenya **Medical Laboratory Technicians and Technologists (Fees) Regulations 2006** contained in Legal Notice No. 14/2006 shows the classification of and registration of laboratories, including private laboratories and fees payable.
36. Relevant still, are the Medical Laboratory (Equipment and Reagents Validation) Regulations, 2011 whose purpose is to regulate the quality of medical laboratory equipment and reagents through a detailed defined validation process. The regulations target at the first instance the manufacturers of the laboratory equipment and reagents; and, in the second instance, the users of such equipment and reagents. **Regulation 2** defines the validation as:- “the process of authentication undertaken by Board or its appointed agents for the purposes of confirming the quality of medical laboratory reagents and equipment by performing tests to confirm the information provided by the manufacturers relating to their precision, linearity, specificity, sensitivity and accuracy in the description of the equipment reagents and chemicals for use within medical laboratories in Kenya”
37. Regulation 3(i) prohibits any laboratory technician or technologist from stocking or using any unvalidated equipment or reagents within medical laboratories. The Regulation also requires laboratory technicians and technologists to maintain a record in their premises of certificates of validation issued by the Board. The duty to ensure compliance with validation standards is extended to proprietors of medical laboratories under Regulation 13. Sub Regulation 3 makes it mandatory for all medical laboratories to use validated equipment and reagents.
38. These Regulations to my understanding apply to all facilities where medical laboratory analysis is carried out and these include laboratories in hospitals whether public or private. This conclusion is informed by the following definitions of various laboratories:
- (a) Hospital laboratory** – as per **Act No. 10 of 1999** is a “*facility in a health institution in which medical laboratory analysis and investigations are carried out.*”
- (b) Medical laboratory** as per **Act No. 10 of 1999** includes “*any facility where medical laboratory analysis and investigations are carried out and includes a hospital laboratory.*”
39. It is clear from this definition that a hospital and laboratory are regarded as separate institutions. It cannot therefore be said that to inspect a medical laboratory is equivalent to inspecting the hospital and neither can it be said that the regulations made under the Act are *ultra vires* the Act as they are made pursuant to **Section 25 and 40 of the Act**. Further, from the provisions I have out

above and my extensive reading of the Act, I have found no provision in either the Act or the Regulations made thereunder that exempt the private medical laboratories from the operation of the Act. It is also clear from the provisions of **Act No. 10 of 1999** which I have quoted in *extenso* that the Act confers on the Medical Laboratory Technicians and Technologists Board the power to regulate not only the personnel in the field of medical laboratory but the clinical/medical laboratories that offer the services as well.

40. Whereas the object of the Act does not expressly state the regulations of clinical laboratories, and for that matter laboratories under private hospitals, it would be incongruous to conclude that the same were exempted from the operation of the Act. Indeed I would consider the want of express inclusion of the regulatory function in the objections of the Act as a product of poor drafting and not lack of intent by Parliament to have all facilities whether public or private which offer medical laboratory services regulated and more so by one body. While I recognize that it is not within court's jurisdiction in the present application to adjudge the merits of the decisions being challenged before me, I find that a contrary interpretation of the Act would lead to the undesired result that persons seeking medical laboratory services from private institutions would be left exposed to the perils of an unregulated practice and service delivery. That would not only be discriminatory but go against the public interest and make nonsense of the principle that law should serve the public interest. (See **Francois Bennion** (*supra*))

(ii) Whether the power to register, license and regulate the business and practice of private medical laboratories vests in the Medical Practitioners and Dentists' Board or the Medical Laboratory Technicians and Technologists Board or concurrently in both Boards.

41. As stated earlier in this Ruling, the Applicants' argument is that private medical practitioners are subject to the exclusive regulatory framework provided in the Medical Practitioners and Dentists Act. With respect to medical laboratory practice, it is their argument that the regulatory framework is provided for under the **Medical Practitioners and Dentist's (Private Practice) Rules** made under the Act.

42. On the other hand, the Respondents' argument is that the Rules made under the **Medical Practitioners and Dentist's Act** cannot oust the express provisions of **Act No. 10 of 1999** and that even if the Rules were to apply, they are confined to regulation of private medical practitioners who are qualified pathologists.

43. In order to make a finding on this issue, I have considered the provisions of the Medical Practitioners and Dentists Act beyond the few provisions cited to me by the parties. The Preamble of the **Medical Practitioners and Dentists Act** captures its scope as:-  
"An Act of Parliament to consolidate and amend the law to make provision for the registration of medical practitioners and dentists and for purposes connected therewith and incidental thereto"

44. This Act creates the Medical Practitioners and Dentists Board in **Section 4**, as a body corporate with perpetual succession and a common seal, and shall be capable in its corporate name of suing and being sued; acquiring, holding and disposing of property; and borrowing and lending money. The functions of the Board are variously provided for in the Act including supervisory functions over the quality of standards of training of medicine and dentistry (**Section 11A**), authorizing the registration of qualified persons as medical practitioners or dentists (**Section 11, 13**), licensing of a person to render medical or dental services (**Sections 15**), disciplinary functions (**Section 20**), licensing practitioners to engage in private practice (**Section 15**); regulating the practice of medicine and dentistry (**Section 22**).

45. With respect to the issues in this application, I observe that the Act does not provide in the substantive provisions for the regulation of laboratory services. This issue is covered under the **Medical Practitioners and Dentists (Private Practice) Rules (hereinafter the Rules)** made under the Act, which provide the following relevant definitions:

"approved clinical laboratory" means a private clinical laboratory which is covered on a full-

time basis by a pathologist and is so equipped as to enable the carrying out therein of investigations in clinical chemistry, haematology and microbiology

“clinical laboratory” means premises for examining specimens for the purpose of providing information on diagnosis, treatment or prevention of disease;

“hospital” means an institution which has, in addition to resident medical practitioners or dentists, an operating theatre and a mortuary;

“laboratory medicine” means the practice of all or any of the following disciplines, namely pathology, clinical chemistry, microbiology and parasitology, haematology, morbid anatomy and histology, cystology, immune-pathology, forensic pathology and other disciplines relevant thereto;

“pathologist” means a specialist in one or all of the disciplines in clinical laboratory medicine; -

“private practice” means giving medical, surgical or dental advice, attendance or performing an operation, or engaging in radiological or clinical laboratory medicine, for a fee;

“single discipline pathologist” means a medically qualified person whose training has not covered all the disciplines of clinical laboratory medicine, but who is a specialist in any of the disciplines in pathology;

“specialist” means a medical practitioner or dentist who has completed an approved training programme in a particular discipline in medicine or dentistry, and who has acquired a recognized postgraduate qualification or its equivalent, and who thereafter has gained sufficient experience and shown to the Board’s satisfaction adequate clinical, radiological or laboratory skill, in his chosen discipline;

“specialist practice” means the practice of medicine or dentistry in a specialized discipline as specified in these Rules.

8. In this Part, “licensee” means a medical practitioner or dentist licensed to operate a private clinic under rule 9.”

46. The Rules contain extensive provisions for the licensing of private practitioners. Pertinent to this application are provisions relating to qualification, licensing, minimum laboratory standards and inspection of laboratories. The definition of approved clinical laboratory shows that only a medical practitioner who is a qualified pathologist is eligible to offer laboratory services. A pathologist is a medical practitioner who has specialized in one or all of the disciplines in clinical laboratory medicine. It follows that a medical practitioner only qualifies to run a clinical laboratory upon acquiring specialized knowledge in pathology. **Rule 27 (i)** states that the Board may grant a licence in the Form VII set out in the Medical Practitioners and Dentists (Forms and Fees) Rules to a medical practitioner to practice private clinical laboratory medicine if the practitioner is both eligible under Rule 3 and a pathologist.

47. **Rule 17** restricts the licensing of clinical laboratories in a private clinic to only those manned by the private practitioner. It states that:-

“A private clinic may not include a clinical laboratory unless –

- a. examination of the specimens obtained from patients in that laboratory is undertaken by the private practitioner personally or a qualified medical laboratory technician or technologist;
- b. examinations are limited with the way prescribed in paragraph (3)” It is clear from this definition of an approved clinical laboratory that such a laboratory must be covered on a full time basis by a pathologist while under **Rule 29** a clinical laboratory must at all times be supervised by a

pathologist. **Rule 27 (2)** provides for the publication of a list of private clinical laboratories while **Rule 29 (2)** gives the Board the mandate to inspect any premises used as a clinical laboratory at any reasonable time.

48. From the Rules cited above, it is manifestly clear that the Medical Practitioners and Dentists Board has carved for itself a regulatory function over private medical laboratories. The question to be answered then is whether this function ousts the jurisdiction of the Board under **Act No. 10 of 1999** which, as I have found, is not limited to public institutions but extends to private medical laboratories.
49. A cardinal rule of statutory construction and interpretation is that subsidiary legislation cannot override the substantive provisions of a statute and where there is conflict then the subsidiary legislation must give way to the substantive provisions. The scenario in this application is even more remote as the Rules in question are made under the **Medical Practitioners and Dentists Act** and not under **Act No. 10 of 1999**. My view is that these Rules are only useful to the extent of aiding the medical profession in its noble task of self-regulation but cannot oust the statutory mandate of the Respondent. They can only augment it.
50. Even if I were to hold the position that the Rules confer on the **Medical Practitioners and Dentists Board** a regulatory mandate over private clinical and medical laboratories, the legal position would still be that such regulation would be limited to private practitioners who are qualified pathologists. The issue then in the present application would be whether the applicants are qualified pathologists so as to qualify for licensing and regulation of their medical laboratories by the Medical Practitioners and Dentists Board, as per the Rules already cited above.
51. From the material before court, none of the applicants have demonstrated that they are qualified pathologists themselves or have in their employ qualified pathologists who cover the laboratories on a full time basis as required by the Rules. They cannot therefore purport to be regulated by the Board when they are not qualified according to the Rules. However, even if there was material to demonstrate such qualification, I would still hold that they would then be subject to a concurrent regulatory framework because, as I have found earlier in this judgment, the laboratory technicians and technologists in the applicants' employ as well as the laboratories that they work in are clearly subject to the regulatory mandate of the Respondent. I do however agree with the applicants that double licensing and the attendant costs is punitive and would urge that the Ministry responsible for both Boards moves quickly to administratively offer policy guidelines on which Board should receive the fees.

(iii) Whether due process was followed in issuing the notices of compliance and closure.

52. Having found that the Respondent was within its mandate to inspect the applicants' medical laboratories and consequently to issue the relevant notices pursuant thereto, I now deal with the question whether the Respondent followed due process in executing its mandate. As indicated earlier the Respondent inspected the Applicants' facilities on diverse dates in August 2011 and issued various notices consequent upon the shortcomings that the inspection revealed. The Applicants' complaint in their Statement of Judicial Review is that they were not given an opportunity to be heard prior to the decision.
53. I find nothing unfair in this as all that the Respondent did was to carry out inspection, document the shortcomings in the laboratories and issue notices for appropriate corrective measures. It is apparent from the notices issued that the Applicants were given time to comply. The notices were clearly signed by officers in the Applicants' institutions showing some level of participation in the inspection process. Further, from the material before court, I have no doubt that the Applicants were aware of an appeal process provided in the Respondents' Manual which they failed to utilize thereby denying themselves a forum for further engagement with the Respondent before a final decision as taken. In the circumstances, I am unable to fault the process. The Applicants have not demonstrated any missteps by the Respondent in inspecting the Medical Laboratories and issuing the notices.
54. A related complaint by the Applicants' is that the Respondent threatened to close the Applicant's' hospitals. As has been demonstrated elsewhere in this judgment, clinical and/or medical laboratories are distinct from hospitals. I agree with the strong submission by the Respondent that

the Applicants have attempted to mislead the court by alleging that the Respondent intended to close the Applicants' hospitals. It is my finding that both the inspection and the notices consequent thereupon were directed at the clinical and/or medical laboratories and not the hospitals. The attempt to mislead the court must therefore be met with censure.

55. In conclusion, and from the extensive reasoning above, I find that the orders sought by the Applicants cannot be granted.

56. I order that the Respondent do carry out a fresh inspection of the applicants' clinical and/or medical laboratories and issue appropriate 30 day compliance notices in accordance with the law.

57. Having so ruled however, I direct that this judgment be brought to the attention of the Cabinet Secretary responsible for Health Services with the expectation that it will trigger appropriate legislative reform to comprehensively address the regulation of this all important sector of medical laboratory services.

The application is dismissed with costs to the Respondent.

**Judgment dated and signed at Nairobi this .....day of August, 2013**

**R. LAGAT - KORIR**

**JUDGE**

**Judgment delivered, dated and signed at Kisii this 21st day of August 2013.**

**R. N. SITATI**

**JUDGE**

**In the presence of:**

Bibu : Court clerk

Mr. Oguttu : Counsel for the Applicants

Mr. Mwangeli : Counsel for the Respondents