Pharmacy and Poisons Board v Wanjala & 7 others (Civil Appeal 211 of 2017) [2021] KECA 348 (KLR) (17 December 2021) (Judgment)

Neutral citation: [2021] KECA 348 (KLR)

REPUBLIC OF KENYA

IN THE COURT OF APPEAL AT NAIROBI

CIVIL APPEAL 211 OF 2017

W KARANJA, M NGUGI & P NYAMWEYA, JJA

DECEMBER 17, 2021

BETWEEN

PHARMACY AND POISONS BOARD ..... APPELLANT

AND

PIUS WANJALA ..... 1ST RESPONDENT

MINISTRY OF HEALTH ..... 2ND RESPONDENT

CLEOPHAS MAILU ..... 3RD RESPONDENT

NICHOLAS MURAGURI ..... 4TH RESPONDENT

NATIONAL QUALITY CONTROL LABARATORY ..... 5TH RESPONDENT

ATTORNEY GENERAL ..... 6TH RESPONDENT

FEDERATION OF KENYA PHARMACEUTICAL MANUFACTURERS .... 7TH RESPONDENT

PHARMACEUTICAL SOCIETY OF KENYA ..... 8TH RESPONDENT

(An Appeal from the judgment and decree of the High Court of Kenya at Nairobi (G.V. Odunga J) dated 16th March 2017 in Judicial Review Miscellaneous Civil Application No. 159 of 2016)

Role of the National Quality Control Laboratory vis-a-vis the Pharmacy and Poisons Board.

Reported by Kakai Toili

Medical Law *– medical institutions - National Quality Control Laboratory vis-a-vis the Pharmacy and Poisons Board - role of the National Quality Control Laboratory vis-a-vis the Pharmacy and Poisons Board - whether the National Quality Control Laboratory had the powers of inspection of premises and issuance of certificates of compliance with good manufacturing practices – Pharmacy and Poisons Act (cap 244) sections 35C, 35D, 35E and 35F; Clinical Officers (Training, Registration and Licensing) Act, 2017, section 34.*

Brief facts

On March 10, 2016, the 4th respondent issued a circular (the circular) in which he directed the Director of the National Quality Control Laboratory (the Director) to stop implementing the functions set out in sections 35A(5) and 35I(b) of the Pharmacy and Poisons Act (the Act) relating to inspection of premises and issuance of certificates of compliance with good manufacturing practices (GMP), by sampling any medicinal substance under production in any premises to certify that the approved method of manufacture was being followed. The reason for the circular was that rule 10 of the Pharmacy and Poisons (Registrations of Drugs) Rules (the Rules) empowered the appellant to carry out the function.

The 1st respondent's case before the trial court was that rule 10 of the Rules was unlawful as it contravened section 35A(5) and 35I(b) of the Act. The appellant argued that the creation of the 5th respondent, the National Quality Control Laboratory (the Laboratory) under Part 111B of the Act was as a testing facility to support the appellant as outlined under section 35D, and not to complement it.

The appellant's case was that it carried out a comprehensive inspection to confirm compliance with GMP while the Laboratory carried out an inspection to sample and certify that the method of manufacture approved by the appellant was followed. The trial court held, *inter alia*, that the Laboratory was the relevant agency to carry out the inspections provided for under rule 10 of the Rules. The appellant was dissatisfied with the decision of the trial court and thus filed the instant appeal.

Issues

i. What was the role of the National Quality Control Laboratory *vis-a-vis* the Pharmacy and Poisons Board?

ii. Whether the National Quality Control Laboratory had the powers to the inspection of premises and issuance of certificates of compliance with good manufacturing practices.

Held

1. Whilst an appellate court had jurisdiction to review the evidence to determine whether the conclusions of the trial court should stand, that jurisdiction was exercised with caution; if there was no evidence to support a particular conclusion, or if it was shown that the trial court had failed to appreciate the weight or bearing of circumstances admitted or proved, or had plainly gone wrong, the appellate court would not hesitate to make that decision.
2. By section 34 of Act No. 20 of 2017 (Clinical Officers (Training, Registration and Licensing) Act, 2017), Parliament repealed the provisions that were the subject of the instant litigation. The effect of those amendments was to vest the powers of inspection and issuance of GMP compliance in the appellant, thus achieving the effect that the 4th respondent's circular impugned in the application before the trial court sought to achieve.
3. The Legislature had, long before the instant appeal was canvassed, addressed the issue of who, between the appellant and the Laboratory, had the legislative mandate to carry out GMP inspections under the provisions of the Pharmacy and Poisons Act. Substantively, therefore, the appellant's appeal on that issue had been rendered moot.
4. While the trial court had held that the Laboratory was the relevant agency under rule 10 of the Rules, the use of the term 'facility' in section 35D(1) of the Act indicated that the intention of the Legislature was to create an organ, subordinate to or within the control of the appellant, to carry out functions delegated to it by the appellant of sampling medicines. The intention was not to create a complementary or independent body. The Laboratory was not established as a second regulatory body but as a facility within the Board with its functions and management under the control of the appellant.
5. Once the Legislature amended the law to vest the functions in section 35 solely on the appellant, it also rendered the appeal with regard to rule 10 of the Rules moot- all the functions under the Act would be performed by the appellant, with the Laboratory operating as a facility within the control of the appellant.

Appeal allowed.

Orders

Each party to bear its own costs of the trial in the High Court and of the instant appeal.

Citations

Cases

1. Henry N.Gichuru vs The Ministry of Health and The Kenyatta National Hospital Board [2002] eKLR (civil misc appl 417 of 02) — Cited
2. Republic v Kenya Medical Laboratories Technicians and Technologists Board Ex-Parte Archdiocese Nairobi Kenya Registered Trustees (Miscellaneous Application 665 of 2017 [2018] eKLR)
3. Republic v Public Procurement Administrative Review Board & 2 others; Ex-Parte Central Kenya Fresh Merchants Limited (Miscellaneous Civil Application 309 of 2018 [2018] eKLR) — Explained
4. Peters vs Sunday Post Limited ([1958] EA 424) — Explained
5. Selle vs Associated Motor Boat Company Ltd. ([1968] EA 123) — Explained

Statutes

1. Interpretation and General Provisions Act (Cap. 2) — section 31 (b) — Interpreted
2. Pharmacy and Poisons Act (Cap. 244) — section 35 A(5) , 35 I(b), 35D — Interpreted
3. Statutory Instruments Act,2013 — section 24 (2) — Interpreted

Advocates

None mentioned

JUDGMENT

1. In an appeal presented by way of a Memorandum of Appeal dated July 3, 2017, the Pharmacy and Poisons Board (hereafter 'the appellant' or 'the Board') asks this Court to address the question as to who, between the appellant and the 5th respondent, the National Quality Control Laboratory (the Laboratory) has the legislative mandate to carry out Good Manufacturing Practices (GMP) inspections under the provisions of the *Pharmacy and Poisons Act*, Cap 244 Laws of Kenya (hereafter 'the Act') and rule 10 of the *Pharmacy and Poisons (Registrations of Drugs) Rules* (hereafter 'The Rules'.).

2. The appeal arises from the decision of the High Court of Kenya at Nairobi (Odunga J) dated March 16, 2017 in which the court held, inter alia, that the Laboratory is the relevant agency to carry out the inspections provided for under rule 10 of the Rules.

3. The decision was rendered following an application by the 1st respondent brought by way of notice of motion dated April 6, 2016 in which he sought the following substantive orders:

    1. An order of *certiorari* to have the decision of the 3rd respondent, 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 35A(5) and 35I(b) of the *Pharmacy and Poisons Act*, cap 244 Laws of Kenya, removed into the High Court for purposes of its being quashed;

    2. An 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. An order of prohibition to prohibit and restrain the 4th respondent (Pharmacy and Poisons Board) from acting upon the 3rd respondent's circular of March 10, 2016 by usurping the functions of the 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. An order of *mandamus* to compel the 5th Respondent (National Quality Control Laboratory) to perform its functions as conferred in Sections 35 A (5) and 35 I (b) of the *Pharmacy and Poisons Act*, cap 244 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.

4. In the decision impugned in this appeal, the trial court issued three orders. The first was a declaration that the decision of the 4th respondent, the Principal Secretary, Ministry of Health vide circular Ref: MOH/ADM/1/2/17/VOL.I of March 10, 2016 stopping the Laboratory from performing the functions conferred by section 35 A(5) and 35 I(b) of the Act, was unlawful. It issued, secondly, an order of prohibition prohibiting and restraining the appellant from usurping the functions of the Laboratory of inspecting premises and issuing certificates of compliance to Good Manufacturing Practices 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 Act, as well as those under section 35D of analytical testing of medicinal samples.

5. The court finally issued an order of *mandamus* to compel the Laboratory to perform its functions as conferred in sections 35 A (5) and 35 I (b) of the Act 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.

6. The appellant was dissatisfied with the decision of the trial court. It filed the present appeal in which it raised a total of 12 grounds of appeal in its memorandum of appeal dated July 3, 2017. In its submissions before us, the appellant reduced the 12 grounds to three issues, which encompassed the substance of its appeal, as follows:

   a. Whether the learned judge of the High Court made a fundamental error of fact and law in determining that the 5th respondent's mandate to inspect premises under sections 35A and 351 (b) of the *Pharmacy and Poisons Act* amounts to an inspection for Good Manufacturing Practices. (Ground 5, 8, and 11)

   b. Whether the learned judge of the High Court properly exercised his discretion in determining that the National Quality Control Laboratory, the 5th respondent herein (hereinafter "the Laboratory"), is the relevant agency to carry out the inspections provided under rule 10 of the *Pharmacy and Poisons (Registration of Drugs) Rules* (Grounds 1, 2, 6, and 7);

c. Whether the Order of the Trial Court, in the form of an Order of Prohibition on the exercise of the Board's mandate with respect to issue of GMP Compliance Certificates, is in excess of its jurisdiction in judicial review proceedings? (Grounds 3, 4, 9, 10, and 12).

7. Before considering the appellant's appeal and the submissions of the parties with respect thereto, however, it is useful to remind ourselves of the mandate of this court on a first appeal. As was held in *Peters vs Sunday Post Limited* [1958] EA 424,

> "Whilst an appellate court has jurisdiction to review the evidence to determine whether the conclusions of the trial judge should stand, this jurisdiction is exercised with caution; if there is no evidence to support a particular conclusion, or if it is shown that the trial judge has failed to appreciate the weight or bearing of circumstances admitted or proved, or has plainly gone wrong, the appellate court will not hesitate so to decide."
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> See also *Selle vs Associated Motor Boat Company Ltd*., [1968] EA 123.

8. The background to the present appeal and the facts forming the basis of the case before the trial court were as follows. On March 10, 2016, the Principal Secretary, Ministry of Health, the 4th respondent, issued a circular Ref: MOH/ADM/1/217/Vol.1 in which he directed the Director of the Laboratory to stop implementing the functions set out in section 35A (5) and 35 1 (b) of the Act relating to inspection of premises and issuance of Certificates of Compliance with Good Manufacturing Practices, by sampling any medicinal substance under production in any premises to certify that the approved method of manufacture is being followed.

9. The reason for the circular was that Rule 10 of the Rules empowers the appellant to carry out the said function. The circular was further based on the rationale that Kenya has only one single medicines regulatory body, the appellant, and it is the one that should perform the functions of inspection of the premises and issuance of certificates of compliance to Good Manufacturing Practices by sampling any medicinal substance produced in any manufacturing premises to certify that the approved method of manufacturing is being followed in line with global practices and the harmonization of East Africa as provided under section 35A (1) of the Act.

10. Upon receipt of the circular, the 1st respondent, then a Senior Deputy Director of the Laboratory, took the view that the circular was whimsical, unconstitutional and illegal as it purported to amend specific statutory provisions without going through Parliament. The 1st respondent's case before the trial court therefore, was that rule 10 of the Rules was unlawful as it contravened section 35 A (5) and 35 I(b) of the Act. It was also his case that a scrutiny of the two Gazette Notices pertaining to the issue – Legal Notice No. 142 of 1991 and 147 of 1981- showed that the said rule 10 of the Rules was not gazetted under the said notices. It was therefore a nullity ab initio by virtue of section 24 (2) of the *Statutory Instruments Act* and section 31 (b) of the *Interpretation and General Provisions Act*. The 1st respondent's position was supported by the Laboratory.

11. In opposing the application, the Ministry of Health, the then Cabinet Secretary for Health and the Attorney General (the 2nd, 3rd and 6th respondents) noted that there was no decision to be quashed as the impugned circular had been withdrawn on June 29, 2016. Regarding the prayer to quash Gazette Notice Nos. 147 of 1981 and 142 of 1991, these respondents took the position that the 1st respondent had not provided any grounds for quashing the said Gazette Notices.

12. The appellant's case before the trial court was, first, that the court had no jurisdiction to adjudicate on the matter before it as the 4th respondent had withdrawn the circular in contention by his letter dated

June 29, 2016. Accordingly, prayers a) c) and d) of the 1st respondent's application had been overtaken by events.

13. It was its contention, secondly, that the 1st respondent had not annexed to his application Gazette Notices Nos. 147 of 1981 and 142 of 1991 which he was seeking the quashing of. Further, since the notices the 1st respondent was seeking to quash had been issued more than 30 years before, they were not capable of quashing under the provisions of order 53 of the *Civil Procedure Code* and the prayers were barred under the statutory doctrine of laches. It was also the appellant's position before the trial court that the legality of legislation could only be dealt with through a constitutional petition, not through judicial review which dealt with administrative action under article 47. The appellant further denied usurping the powers of the Laboratory. Its case was that the Laboratory was established under section 35D of the Act as a facility to support the appellant, and not as a complementary body to the appellant.

14. According to the appellant, section 35A and 35B (Part 111A) of the Act titled 'Manufacture of Medicinal Substances' spoke of licensing of manufacturers of medicinal substances located within Kenya by the appellant and therefore should not be extended to licensing of manufacturers of medicinal substances by National Medicines Regulatory Authorities (NMRAs) of countries where the companies are located. It contended that the sections only cover manufacturers based in Kenya as they are the only manufacturers licensed by the appellant. The Act did not have international jurisdiction and the appellant did not and could not licence foreign manufacturers.

15. It could only recognise valid licences issued by their respective NMRAs equivalent to the appellant in addition to the GMP certification carried out by the appellant. The appellant therefore denied that it had usurped the powers of the Laboratory. It argued that the creation of the Laboratory under Part 111B of the Act was as a testing facility to support the appellant as outlined under section 35D, and not to complement it.

16. According to the appellant, the powers granted to the Laboratory under section 35A (5) and 35 1(b) are not applied in isolation but to enable the Directors of the Laboratory to effectively undertake its mandate under section 35D of the Act. The Laboratory and its staff members had not been stopped from entering any manufacturing premises within Kenya for purposes of certifying that the method of manufacture approved by the appellant was being followed in fulfilment of the Laboratory's mandate under section 35D of the Act.

17. It was the appellant's case before the trial court further that the role of the Laboratory relating to 'manufacturing premises' had been categorically spelt out under section 35A (5). Such role is limited to inspection with a view to sampling and certifying that the method of manufacture approved by the appellant was being followed as opposed to a comprehensive inspection to confirm compliance with GMP of entire sections of the manufacturing premises, which is carried out by the appellant.

18. The appellant's case therefore was that it carries out comprehensive inspection to confirm compliance with GMP while the Laboratory carries out inspection to sample and certify that the method of manufacture approved by the Board is followed. There was therefore no conflict between section 35A and 35B regarding the functions of the Laboratory in fulfilling its mandate under section 35D and the provisions of rule 10 of the Rules which speaks to GMP inspection as a pre-requisite to registration of a drug in Kenya.

19. The appellant and the 1st respondent filed written submissions in support of their respective positions on the appeal. Learned Counsel, Mr. Sisule, highlighted the appellant's case, while Mr. Wanjala, the

1st respondent herein, presented his case in opposition to the appeal. The other respondents did not participate in the appeal.

20. In its submissions, the appellant raised 3 issues for determination which it indicated were a consolidation of the 12 grounds raised in the Memorandum of Appeal. The first is whether the trial court had made a fundamental error of fact and law in determining that the Laboratory's mandate to inspect premises under section 34A and 35 I (b) of the Act amounts to an inspection for Good Manufacturing Practices. The second was whether the trial court properly exercised its discretion in determining that the Laboratory is the relevant agency to carry out the inspections provided under rule 10 of the Rules. Finally, whether the order of the trial court in the form of an order of prohibition on the exercise of the appellant's mandate with respect to issue of GMP Compliance certificates is in excess of its jurisdiction in judicial review proceedings.

21. On the first issue, the appellant asks the court to interfere with the discretion of the trial court as the principles for such interference set in *Coffee Board of Kenya v Thika Coffee Mills Limited & 2 others*[2014] eKLR have been met.Further, that the trial court exercised its discretion wrongly and arrived at a wrong decision in concluding that the mandate of the Laboratory under section 35A (5) and 35 1 (b) amounts to an inspection for GMP, which in its view it does not.

22. The appellant further submits that in exercise of its powers under section 35B of the Act, it has prescribed the World Health Organisation (WHO) Good Manufacturing Practice to the GMP standard for the manufacture of medicinal substances which are either manufactured locally or imported into the country. That it relies on the World Health Organisation Compendium of Guidelines and related materials – Good Manufacturing Practices and Inspections (WHO Compendium) to define GMP.

23. Relying on the WHO compendium definition of GMP and its requirements, the appellant submits that the WHO Compendium Guidelines define GMP as a complete and sequential quality assurance system of the whole process in which pharmaceutical products interact with various players before reaching the end consumer, from the sourcing of raw materials to be used in the manufacture of the pharmaceutical products to the logistics of supply chain distribution and storage.

24. It is its submission that GMP inspection involves a wide array of factors that an inspector has to take into account before making recommendations on compliance. The 1st respondent had therefore misled the court by alleging that the Laboratory is mandated to inspect premises and issue certificate of compliance to 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 under section 35A (5) and 35 1 (b). The appellant submits that GMP compliance inspection is not limited to simply 'sampling any medicinal substance under production' but entails multiple considerations.

25. The appellant submits further that in accordance with WHO Guidelines on Manufacturer's Drug Distribution Channels, GMP inspection also involves inspection of drug distribution channels. Taking samples for the purpose of testing by the official quality control laboratory is only one of the multiple consideration taken into account when conducting GMP inspection.

26. Accordingly, it is the appellant's submission that the trial court misled itself in reaching the conclusion that the inspection carried out by the Laboratory pursuant to section 35A (5) is sufficient to be considered an inspection for GMP certification. A consideration of the functions of the Laboratory under the Act, which reflect the intention and purpose of the legislature in establishing the Laboratory, cannot be considered sufficient to satisfy the significant task that is GMP Compliance Inspection.

27. The appellant submits that the Laboratory has not been restrained in the exercise of its mandate under section 35A (5) which is to enter into premises and 'certify that the method of manufacture approved by the Board is being followed'. It contends that in interpreting the mandate of the Laboratory under the Act, the court should apply the golden rule of construction that requires that in construing a statute, the words used in the statute must be given their ordinary, literal, and grammatical meaning, more so where the words are clear and unambiguous. Reference is made for this submission to the case of *Republic v Kenya Medical Laboratories Technicians and Technologist Board ex parte Archdiocese of Nairobi Kenya Registered Trustees* and *Henry N.Gichuru vs The Ministry of Health and The Kenyatta National Hospital Board (2002) eKLR*.

28. The appellant submits that the Laboratory's power of inspection is only referred to in section 35A (5) and 35 1 (b) of the Act. The appellant takes the view that the legislative intent and purpose under section 35 1 (b) is evident from the language. The section gives the Director of the Laboratory the mandate to enter into premises and sample any medicinal substance under production for the purpose of certifying that the method of manufacture approved by the appellant is being followed and upon satisfaction, issue a certificate of compliance with the method of Good Manufacturing Practices approved by the appellant.

29. In its view, this interpretation is in accordance with the function of the Laboratory as a facility for 'sampling, examination and testing' for the purpose of performing chemical, biological, biochemical, physiological and pharmacological analysis as provided under section 35D (1) of the Act. The trial court had therefore erred in holding that the inspection under sections 35A (5) and 35 1 (b) amounted to an inspection for the purpose of GMP compliance.

30. On the second issue, the appellant cites three reasons for its contention that the trial court misdirected itself in holding that the Laboratory is the relevant agency under Rule 10 of the Rules. The first is that the context in which Rule 10 is couched relates to the pre-registration stage of a drug that is to be manufactured locally or imported into Kenya, and active production of the drug is yet to commence. Sections 35A (5) and 35D (1) of the Act, on the other hand, establish the Laboratory principally for the sampling of drugs in active production for the purpose of examination and testing with a view to determine either the method of manufacturer for chemical, biological, biochemical, physiological and pharmacological analysis.

31. The second reason advanced is that inspection under Rule 10 is for the purpose of inspecting the plant and the process of manufacture intended to be employed in the manufacture of the drug, a function that is distinguishable from the role of the Laboratory of analysis of the (proposed) drug to ascertain safety, efficacy quality and economic value for the purpose of registration as provided under section 35D (1) (c). The appellant submits that the function of assessing the plant and process of manufacture, especially with regard to technical capacity and resources such as qualified personnel, is beyond the functions of the Laboratory under the Act.

32. Its third reason for impugning the decision of the trial court is that in prescribing the Laboratory as the relevant agency under Rule 10, the trial court limits unjustly the discretion vested on the appellant by the Rules. In the view of the appellant, this limit on its discretion is unnecessary in the absence of proof of abuse of its discretion. The appellant submits that courts should be hesitant to usurp the discretion of administrative bodies where abuse is neither alleged nor proved. Reliance for this submission is placed on the decision in *Republic v Public Procurement Administrative Review Board & 2 others ex parte Central Kenya Fresh Merchants Limited (2008) eKLR*.

33. In response to the last issue whether the trial court exceeded its jurisdiction in issuing an order of prohibition with respect to the issue of GMP compliance, the appellant submits that the trial court

had misconstrued the provisions of the Act with the result that it usurped the appellant's mandate. Further, that under sections 35A and 35B of the Act, the appellant is empowered to impose conditions on the renewal of the licence to manufacture medicinal substances. Its submission is that the conditions for renewal can only be based on GMP compliance as provided under section 35B. Accordingly, the finding that the Laboratory is the relevant agency for conducting GMP inspections and issuing compliance certificates results in usurpation of the appellant's power to impose conditions on renewal under section 35A (2). Where, as the decision of the court would imply, the Laboratory has issued a compliance certificate, the appellant is reduced to rubber-stamping the decision of the Laboratory.

34. The appellant submits that the trial court had erred in its finding that the Laboratory and the appellant had complementary roles. It notes that the trial court had observed that under section 35 1(c), the Director of the Laboratory is empowered to advise and obtain advice from the Board, and had concluded that the 'Board' referred to in the section is the appellant. However, according to the appellant, the 'Board' referred to in the section is the Board of management of the Laboratory established under section 35F (1), not the appellant. There is therefore no complementary role established between the appellant and the Laboratory, which is referred to as a 'facility' under section 35D (1) of the Act.

35. In the appellant's view, the erroneous interpretation by the trial court in reaching the conclusion that there was a complementary role between the appellant and the Laboratory led to the usurpation of the appellant's role of GMP compliance and imposing it on the Laboratory, and also usurped the appellant's role of licensing manufacturers as the two roles are inextricably linked. In its view, the court should have refrained from issuing orders of prohibition that had the effect of usurping the discretion and mandate of the appellant.

36. In his written submissions dated June 23, 2021, the 1st respondent identified four issues as arising for determination. The first was whether the trial judge erred in law and fact in determining that section 35 A (5) and 35 I (b) read with 35 B of the Act vest upon the Laboratory the mandate to carry out GMP inspections and to issue certificates of compliance. In addressing this issue, the 1st respondent submits that even assuming that the appellant is correct in its submission that the Laboratory's Good Manufacturing Practices inspection at section 35 A (5) of the Act is narrower in scope than WHO-GMP, the provisions of section 35 I (b) of the Act are general and wide and expand the Laboratory's GMP inspections to unlimited scope.

37. In any event, in the 1st respondent's view, even if the Laboratory's scope of GMP inspections is narrow as the appellant submits, the Act does not give the appellant the right to take over the function from the Laboratory as the appellant's mandate with regard to GMP inspections is limited to prescribing the method of manufacture; and it had done this by adopting WHO-GMP guidelines. The trial court had accordingly correctly determined that the Laboratory is the body vested with the mandate to carry out GMP inspections and issue certificate of compliance.

38. The 1st respondent submits further that the intention of Parliament in creating the Laboratory as a second regulatory body was to address the mischief of inherent conflict of interest in the same body carrying out GMP inspections, issuing certificates of compliance and then relying on the same certificates to licence manufacturing premises. The mandate of the appellant under section 35 A (1-4) was to licence manufacturing premises on the basis of GMP certificates of compliance issued by the Laboratory.

39. The 1st respondent submits that under section 35B of the Act, the mandate of the appellant is to prescribe the method of Good Manufacturing Practices after which the Laboratory enters and inspects the premises to ensure that the GMP prescribed by the appellant are complied with, and to issue the

certificates of compliance with such GMP as required under sections 35A (5), 35B and 351(b) of the Act. In his view, the inspection contemplated under these sections is none other than the inspection for Good Manufacturing Practices.

40. The second issue identified by the 1st respondent is whether the court erred in finding that rule 10 of the Rules is lawful since it supplements sections 35 A (5) and 35 I (b) as read with section 35B of the Act in vesting upon the Laboratory the mandate of carrying out GMP inspection and issuing certificates of compliance. The 1st respondent submits that the trial judge had observed that Rule 10 did not contain provision with respect to whom, between the appellant and the Laboratory, would appoint the inspector under the Rule. The trial court had therefore construed Rule 10 with the necessary alterations, adaptations, qualifications and exceptions necessary to bring it into conformity with the provisions of sections 35 A (5), 35 B and 35 I (b) of the Act and had held that the 'relevant agency' provided for in Rule 10 is the 5th respondent.

41. It is the 1st respondent's position that this interpretation is sound in law and accords with case law, section 24 (2) of the *Statutory Instruments Act* and section 31 (b) of the *Interpretation and General Provisions Act*. In his view, the interpretation sought by the appellant, that Rule 10 grants it the mandate of GMP inspection and issuance of certificates of compliance, would expressly contravene the provisions of sections 35A (5) and 35 I (b) of the Act which confers this mandate to the Laboratory. In his view, such an interpretation would have the effect of nullifying rule 10 for expressly contravening provisions of the parent Act.

42. The 1st respondent asks the Court to consider, thirdly, the issue whether the appellant and the Laboratory can undertake parallel inspections of manufacturers of medicines. The 1st respondent submits that the appellant's contention that the trial court erred in 'failing to appreciate the differentiation of the roles of the appellant of pre-licensing inspections and pre-registration inspections and the 5th respondent in post-licensing and post-registration inspections' is illogical and has no basis in law.

43. It is his submission that under the Act, there can only be one inspector, either the Laboratory or the appellant, to issue certificates of compliance to GMP upon inspection. The 1st respondent challenges this court to either agree with the finding of the trial court or make a declaration in terms of the circular dated March 10, 2016 that precipitated the present litigation and thereby render sections 35 A (5) & 35 1 (b) of the Act superfluous.

44. Finally, the 1st respondent addresses the issue of whether the trial court erred in finding that the Laboratory and the appellant have distinct but complementary statutory mandates and therefore lacked jurisdiction to grant prohibitory orders restraining the appellant from undertaking the GMP inspection and issuance of certificates of compliance. It is the 1st respondent's submission that the trial court was correct in making the finding and in issuing the prohibitory orders. His submission is that the appellant and the Laboratory have individual roles geared towards control of the profession of pharmacy and/or trade in drugs and poisons. Further, that they have complementary roles, with the Laboratory's mandate being issuance of certificates of compliance upon GMP inspections on the basis of the prescribed GMP method prescribed by the appellant as a mandatory requirement to licence medicines manufacturers and also mandatory requirement upon which the appellant registers medicine for trade.

45. We have considered the decision of the trial court and the respective submissions of the parties before us. As we observed elsewhere in this judgment, only the 1st respondent, the *ex parte* applicant before the trial court, filed submissions in response to the appellant's submissions. The Laboratory, which

the trial court found had the mandate to carry out inspections under rule 10 of the Rules, did not participate in the appeal. Its case was advanced by the 1st respondent.

46. A consideration of the grounds of appeal and the submissions of the parties indicates that this appeal revolves around three main issues. The first is with respect to whom, between the appellant and the Laboratory, has the mandate to inspect premises and issue certificates to Good Manufacturing Practices (GMP). This was the central issue before the trial court. The 1st respondent and the Laboratory advanced the position, which the trial court accepted, that it was the Laboratory which had this mandate. In their view, the legislature had created, in the 1992 amendments to the Pharmacy and Poisons Board Act, two independent institutions, the Board and the Laboratory, with distinct mandates. With the March 10, 2016 circular, the 4th respondent was attempting to take away the mandate of the Laboratory and vest it in the appellant

47. The second issue is whether the appellant and the Laboratory can undertake parallel inspections of manufacturers of medicines. The final issue relates to whom, between the appellant and the Laboratory, is the relevant agency for carrying out the inspections provided under rule 10 of the Rules.

48. These are the issues we would have addressed our minds to in this appeal. However, at the hearing of this appeal, Learned Counsel for the appellant, Mr Sisule, informed the Court that the first two issues had been resolved. He did not elaborate, and this point was not addressed by the 1st respondent, either in his oral submissions, or in the written submissions filed in opposition to the appeal. It would appear, however, that the resolution of the issues that Counsel for the appellant was alluding to were the legislative changes made to the *Pharmacy and Poisons Act* subsequent to the decision of the trial court on this matter.

49. By section 34 of Act No 20 of 2017 (*The Clinical Officers (Training,Registration and Licensing) Act, 2017*) dated June 23, 2017, Parliament repealed the provisions that were the subject of the present litigation. The section provides as follows:

> " 34. The *Pharmacy and Poisons Act* is amended— (a) in section 35A by deleting the words "The Director of the National Drug Quality Control Laboratory or any member of the Laboratory staff authorized by him" appearing in subsection (5) and substituting therefor the words "The Board or any person authorized in writing by the Board"; and
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> b. in section 35I by deleting paragraph (b).

50. The effect of these amendments was to vest the powers of inspection and issuance of GMP compliance in the appellant, thus achieving the effect that the 4th respondent's circular impugned in the application before the trial court sought to achieve. Accordingly, then, the legislature had, long before the appeal was canvassed before us, addressed the issue to who, between the appellant and the Laboratory, has the legislative mandate to carry out Good Manufacturing Practices (GMP) inspections under the provisions of the *Pharmacy and Poisons Act*. Substantively, therefore, the appellant's appeal on this issue has been rendered moot.

51. Which leaves one issue for determination before us. This is whether the trial court erred in making the finding that the laboratory was the relevant agency under rule 10 of the Rules. A determination of this issue, in our view, lies in a proper appreciation of the intent of the legislature in enacting the provisions of Part IIIB of the Act, which sets up the National Quality Control Laboratory.

For a better appreciation of the intent, however, it is necessary to consider the section against the preceding part, Part IIIA, which addresses the manufacture of medicinal substances and the licensing thereof. Titled 'Manufacture of Medicinal Substances', section 35A thereof provides as follows:

> Licence to manufacture medicinal substances
>
> 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 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 Board or any person authorized in writing by the Board 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.

52. Section 35B contains provisions requiring compliance with good manufacturing practice, defined in section 2 of the Act as follows:

> " Good Manufacturing Practice", also referred to as "GMP", "cGMP" or "current Good Manufacturing Practice" is the part of quality management which ensures that products are consistently produced and controlled according to their intended use as required by the marketing authorization, clinical trial authorization or product specification".

53. The section requires that:

> " Every person who is granted a manufacturing licence under section 35A shall comply with the good manufacturing practices prescribed by the Board."

54. The Laboratory is established under Part IIIB of the Act pursuant to amendments to the Act made by Act No. 12 of 1992. Section 35C of this part defines the Director in the part as "the Director of the National Quality Control Laboratory appointed under section 35H" while the Laboratory refers to the National Quality Control Laboratory established under section 35D, a critical provision for purposes of the present proceedings. Titled "Establishment of the National Drug Quality Control Laboratory", the section provides as follows:

> 1. There shall be established a National Quality Laboratory which shall be used as a facility for—
>
> a. the examination and testing of drugs and any material or substance from or with which and the manner in which drugs may be manufactured, processed or treated and ensuring the quality control of drugs and medicinal substances;

b. performing chemical, biological, bio-chemical, physiological and pharmacological analysis and other pharmaceutical evaluation; and

c. testing, at the request of the Board and on behalf of the Government, of locally manufactured and imported drugs or medicinal substances with a view to determining whether such drugs or medicinal substances comply with this Act or rules made thereunder.

55. The legal status and governance of the Laboratory is provided for under sections 35E and 35F of the Act. Section 35E provides for the incorporation of the Laboratory as a body corporate with perpetual succession and a common seal, with power to sue and be sued in its corporate name and to acquire, hold and dispose of movable and immovable property for its own purposes.

56. With respect to management, section 35F provides as follows:

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.

57. Under the Act, the Board of Management, whose members are appointed by the appellant in this matter, shall, as provided under section 35H, appoint the Director of the Laboratory:

1. The Board of Management shall appoint a Director who shall be the chief executive of the Laboratory responsible to the Board of Management for the day to day management of the Laboratory...

58. Section 35 I contains the powers of the Director of the Laboratory. It provides as follows:

The Director shall have power—

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

...

c. to advise and obtain advice from the Board of Management in regard to any matter within his purview under this Act.

59. The issue in contestation between the appellant and, primarily, the 1st respondent who was advancing the case of the Laboratory is who, between the appellant and the Laboratory, had the statutory mandate to carry out GMP inspections and issue certificates of compliance. The 1st respondent's complaint before the trial court was that by the circular dated March 10, 2016, the Principal; Secretary in the Ministry of Health had stopped the Laboratory from performing the functions conferred by section 35A(5) and 35I(b) of the *Pharmacy and Poisons Act*. In the circular Ref: No. MOH/ADM/1/2/17/ Vol.I dated March 10, 2016, the Principal Secretary stated, *inter alia* as follows:

" Rule 10 of the Pharmacy and Poisons (Registration of Drugs) Rules, empowers the Board to inspect premises in which manufacturing of a drug is proposed to be conducted. The totality of the foregoing mandate is what constitutes GMP and its subsequent certification. This is also in line with the East African Community harmonisation of medicines regulation. In view of the above, it has been decided that the Pharmacy and Poisons Board shall continue conducting the above duties until further advised."

60. The trial court reached two conclusions with respect to rule 10 of the Rules.The first was that, contrary to the contention of the 1st respondent, the said rule was not inconsistent with the provisions of sections 35A and 35 I(b) of the Act. None of the parties has challenged this conclusion. This conclusion was, however, conditional on the second finding of the court, which is that the 'relevant agency' for the purposes of Rule 10 was the Laboratory. The trial court expressed itself on these two issues as follows:

> " 104. In this case rule 10 does not specify who is to carry out the inspection but simply enjoins the Board to ensure that inspection is carried out by the relevant agencies. In this case the relevant agency is the National Quality Control Laboratory. It is therefore my view that rule 10 ought to be read in a manner that enjoins the Board to ensure that the inspection and certification of the relevant premises are inspected by the Laboratory before licences are issued or registrations effected. To that extent I find that rule 10 of the Pharmacy and Poisons (Registration of Drugs) Rules is not inconsistent with the provisions of sections 35A(5) and 35I(b) of the *Pharmacy and Poisons Act*."

61. In considering the issue relating to the 'relevant agency' and the finding of the court that the Laboratory is the relevant agency, it is important to consider the place of the Laboratory vis a vis the appellant. The legislature has, through the amendments set out above, resolved the main issues that arise in the appeal. While the trial court had held that the Laboratory is the relevant agency under rule 10, the use of the term 'facility' in section 35D(1) of the Act indicates that the intention of the legislature was to create an organ, subordinate to or within the control of the appellant, to carry out functions delegated to it by the appellant of sampling medicines. The intention was not to create a complementary or independent body. Contrary to the arguments by the 1st respondent, the Laboratory was not established as a second regulatory body but as a 'facility' within the Board with its functions and management under the control of the appellant.

62. In addition, once the legislature amended the law to vest the functions in section 35 solely on the appellant, it also rendered the appeal with regard to rule 10 moot- all the functions under the Act would be performed by the appellant, with the Laboratory operating as a facility within the control of the appellant.

63. The final issue arising from the appellant's submissions is whether the order of the trial court in the form of an order of prohibition on the exercise of the Board's mandate with respect to issue of GMP compliance certificates, is in excess of its jurisdiction in judicial review proceedings. The appellant submits before us that the trial court exercised its discretion wrongly and arrived at a wrong decision in concluding that the mandate of the Laboratory under section 35A (5) and 35 1 (b) amounts to an inspection for GMP, which in its view it does not.

64. The appellant cites the decision of this Court in *Coffee Board of Kenya v Thika Coffee Mills Limited & 2 others* (*supra*) in which the court considered thecircumstances under which an appellate court will interfere with the exercise of discretion: that it will not do so unless it is satisfied that the trial court misdirected itself in some matter and thereby arrived at a wrong decision, or that it be manifest from the case as a whole that the court was clearly wrong in the exercise of discretion and occasioned injustice. The appellant submits that the function granted to the Laboratory to inspect premises under sections 35A (5) and 351 (b) of the Act does not amount to an inspection for the purposes of Good Manufacturing Practice (GMP) Compliance Certification.

65. We take the view that this issue has also been rendered moot. We have set out above the amendments to the Act effected by section 34 of Act No 20 of 2017 dated June 23, 2017. As we have observed above, the

effect of these amendments is to vest the mandate of GMP inspection and compliance on the appellant, leaving the Laboratory as a 'facility' as provided in section 35D(1) with the technical function of carrying out, 'at the request of the Board and on behalf of the Government' as provided under section 35D(1)(c), the testing of 'locally manufactured and imported drugs or medicinal substances with a view to determining whether such drugs or medicinal substances comply with this Act or rules made thereunder".

66. It appears to us, then, that this appeal had merit given our findings with respect to the role of the Laboratory. The appeal has also now been rendered a largely academic exercise, arising from the legislative amendments set out hereinabove, which now constitute the current law on the issues raised by the appellant and 1st respondent. The combined effect of our findings and the said legislative amendments is that the orders granted by the trial Court are no longer valid, and cannot therefore stand.

67. In the circumstances, we set aside orders (1), (2), (3) and (4) of the judgment by the trial Court dated March 16, 2017, delivered in Nairobi HC Miscellaneous Application No 159 of 2016. Each party shall bear its own costs of the trial in the High Court and of this appeal.

68. Orders accordingly.

DELIVERED AND DATED AT NAIROBI THIS 17TH DAY OF DECEMBER, 2021

W. KARANJA

.....

JUDGE OF APPEAL

MUMBI NGUGI

.....

JUDGE OF APPEAL

P. NYAMWEYA

.....

JUDGE OF APPEAL

I certify that this is a true copy of the original

DEPUTY REGISTRAR