

(2021) 10 KL CK 0004

In the High Court Of Kerala

Case No : Writ Petition (C) Nos. 10997, 11632 Of 2021

Devi Scans (P) Ltd

APPELLANT

Vs

State Of Kerala

RESPONDENT

Date of Decision : 04-10-2021

Acts Referred:

Constitution of India, 1950 — Article 14, 19, 21, 32, 162, 226, 246
Madras Public Health Act, 1939 — Section 81
Travancore-Cochin Public Health Act, 1955 — Section 86
Epidemic Diseases Act, 1897 — Section 2, 2A, 3(2)(c)
Kerala Epidemic Diseases Ordinance, 2020 — Section 4
Drugs and Cosmetics Act, 1940 — Section 3, 3(b)
Disaster Management Act, 2005 — Section 10(2)(i), 10(2)(l), 20, 24, 38, 39, 65, 69, 72
Essential Commodities Act, 1955 — Section 2(a), 2A(2), 3, 3(2)(c), 5

Citation : (2021) 10 KL CK 0004

Hon'ble Judges : T.R.Ravi, J

Bench : Single Bench

Advocate : P.Ravindran, Paul Jacob, Sheru Joseph, Adhil Haris, Srik.Gopalakrishna Kurup, V.Manu, P.Vijayakumar, M.Ajay

Final Decision : Disposed Of

Judgement

T.R.Ravi, J

1. Petitioners in these writ petitions are Diagnostic Laboratories and Research Centres in Kerala, who were conducting various kinds of Covid-19 tests, including RT-PCR tests. Since the prayers in the writ petitions are similar, they are being heard and disposed of together. The exhibits are referred to as they are marked in W.P. (c)No. 10997/2021. The writ petition has been filed seeking to quash Ext.P7 order dated 08.02.2021 and Ext.P10 order dated 30.04.2021, whereby the State has re-fixed the rates of RT-PCR tests chargeable by the private Laboratories in Kerala and Ext.P11 order dated 01.05.2021 issued by the 1st respondent purporting to be under Section 20 read with Sections 24 & 65 of the Disaster Management Act, 2005 to ensure strict adherence to the prescribed

rates for RT-PCR tests as revised from time to time by the State. There is also a prayer for the issuance of a writ of mandamus directing the 1st respondent to issue necessary guidelines/directions/orders to defray the expenses and reimburse to the private laboratories, the loss suffered by them, below the rate fixed in Ext.P7 order dated 08.02.2021 and to have the same paid at the end of each month on furnishing accounts to the appropriate authority. The petitioners have also sought for a declaration that the 1st respondent has no authority or jurisdiction to fix the rates for RT-PCR tests with respect to private laboratories, unless and until they are ready to subsidise the difference between the rates fixed by the State Government and the one prescribed by the 4th respondent Indian Council for Medical Research for Covid-19 tests. Even though the petitioners had sought for an interim stay of the operation of the implementation of Exts.P10 and P11 orders, the same was declined by a learned Single Judge in the order dated 07.05.2021. The petitioners had challenged the interim order in W.A.No.746 of 2021. By judgment dated 21.06.2021, the Division Bench dismissed the appeal leaving open the legal and factual contentions raised by the petitioners and the respondents.

PETITIONERS' BRIEF

2. On 11.03.2020, the Government of India in the Ministry of Home Affairs, Disaster Management Division issued Ext.P20 whereby, in exercise of powers conferred under Section 69 of the Disaster Management Act, 2005, the Union Home Secretary who was the Chairman of the National Executive Committee delegated his powers under Clauses (i) & (l) of sub-section (2) of Section 10 of the Disaster Management Act, 2005 to the Secretary, Ministry of Health and Family Welfare, Government of India, to enhance the preparedness and containment of Novel Corona Virus (Covid-19) and other ancillary matters connected thereto. This was followed by Ext.P21 order dated 21.03.2020, whereby guidelines were laid down by the ICMR for Covid-19 tests in private laboratories in India. Ext.P21 says that the National Task Force recommended that the maximum cost for testing a sample should not exceed ₹ 4,500/-, which may include ₹ 1,500/- as a screening test for suspect cases and an additional ₹ 3,000/- for a confirmation test. It also says that ICMR encourages free or subsidised testing in this hour of National Public Health Emergency. A Public Interest Litigation was initiated before the Hon'ble Supreme Court, invoking Article 32 of the Constitution of India seeking a direction to ensure free of cost testing facility for Covid-19 by all the testing labs, whether private or Government. Soon thereafter, the entire nation went into a lockdown owing to the spread of Covid-19. On 08.04.2020, the Hon'ble Supreme Court directed that the tests relating to Covid-19 whether in approved Government laboratories or approved private laboratories shall be free of cost. It was also directed that Covid-19 tests should be carried out in NABL accredited laboratories or the agencies approved by WHO/ICMR. The above order was modified by the Hon'ble Supreme Court in Ext.P4 order dated 13.04.2020. Ext.P4 has been reported as *Shashank Deo Sudhi v. Union of India & Ors.* In [(2020) 5 SCC 134]. The order

dated 08.4.2020 of the Hon'ble Supreme Court has been reported on page 132 of the very same volume of SCC. The Hon'ble Supreme Court ordered that its earlier order dated 08.04.2020 was intended to make testing in private labs free for economically weaker sections of the society who were unable to afford the payment of testing fee as fixed by ICMR and that it was never intended to make testing free for those who can afford the payment. The Court clarified that private laboratories can continue to charge for testing of Covid-19 from persons who can make payment of the testing fee as fixed by ICMR. It was also held that free testing for Covid-19 shall be available to persons eligible under the Ayushman Bharath Pradhan Manthri Jan Arogya Yojana which has been implemented by the Government of India and any other category of economically weaker sections of the society as notified by the Government for free testing of Covid-19 thereafter. The Government of India was directed to issue necessary guidelines for reimbursement of the cost of free testing of Covid-19 undertaken by private labs and necessary mechanism to defray expenses and reimbursement to the private labs. On 16.04.2020, the Government of Kerala issued Ext.P25 order regarding testing of Covid-19 in the private sector in Kerala. The order contains several guidelines regarding how the tests are to be carried out and the reports of the results are to be generated.

3. On 25.05.2020, the Secretary to the Government of India in the Department of Health and Family Welfare in his capacity as Director General of ICMR, wrote to the Chief Secretaries of all States/Union Territories, stating that the upper ceiling of the rates suggested at ₹ 4,500/- on 17.03.2020 may not be applicable given the evolving prices of the testing commodities and that the State Governments/U.T. Administrations are advised to negotiate with the private labs and fix the mutually agreeable prices for samples being sent by the Government and also for private individuals desirous of testing by these labs. It was thereafter that the Government of Kerala came out with Ext.P1 order dated 02.07.2020. After referring to the directions issued by the Director General, ICMR, Ext.P23 letter from the ICMR and based on the discussions and further detailed analysis, it was ordered that the RT-PCR (Open System) Test are to be priced at ₹ 2,750/-, X Pert NAT Test to be priced at ₹ 3,000/-, True NAT Test Step I to be priced at ₹ 1,500/- and True NAT Test Step II (only for those tested positive in step I) to be priced at ₹ 1,500/-. Ext.P1 order says that the Department had held a meeting on 19.06.2020 with all private laboratories in Kerala performing Covid-19 tests before the issuance of the order.

4. By Ext.P2 order dated 21.10.2020, Ext.P1 order was modified by the Government. The rate for RT-PCR test was fixed at ₹ 2,100/-, for True Nat test at ₹ 2,100/-, for Antigen test at ₹ 625/- and for GeneXpert at ₹ 2,500/-. It was stated in the order that the cost is inclusive of all the personal protective equipment, swabbing charges, and any other charges related to the tests. The petitioners were functioning based on the rates fixed in Ext.P2. While so, on 01.01.2021, the Government issued Ext.P5 order, whereby the rates were again revised and brought down to ₹ 1,500/-. Some of the private labs filed WP(C)

No.255/2021 before this Court and by Ext.P6 judgment dated 14.01.2021, a learned Single Judge disposed of the writ petition with a direction to the 1st respondent to consider the grievance of the petitioners against Ext.P5 order and to decide after affording them an opportunity of hearing. While issuing the directions, this Court had taken note of the fact that the views of the private laboratories were not ascertained before fixing/reducing the rate of charges from ₹ 2,100/- to ₹ 1,500/-, even though the rates were fixed after holding a meeting with the private laboratories on 19.06.2020. After Ext.P6, on 08.02.2021, the Government issued Ext.P7 order. It can be seen from the order that the representatives of the private laboratories were heard. It is stated in the order that the rates were fixed after a thorough market analysis was carried out by the 4th respondent, which showed that there is a reduction of prices of the cost elements involved. The Government re-fixed the maximum rate chargeable for RT-PCR test as ₹ 1,700/- per test. It was stated that the rates are for patients availing the testing services from the Government approved laboratories and the rates of other tests shall continue at the same levels as fixed by the Government Order dated 01.01.2021. However, two months thereafter, the Government issued Ext.P10 order on 30.04.2021. It is stated in the order that KMSCL had arrived at a rate of ₹ 448.20 per test and since the latest market rate for VTM, RNA extraction kits, PCR test kits, and consumables were identified based on the market analysis and taking into account the rates for similar tests in the States of Haryana, Telengana and Utharakhand, which was ₹ 500/- and in Odisha which was ₹ 400, the Government is revising the rates to be applied for conducting RT-PCR test to ₹ 500/- with immediate effect.

5. On 01.05.2021, the Government also issued Ext.P11 order purporting to be under the provisions of the Disaster Management Act, whereby it was ordered that the private laboratories shall perform RT-PCR tests for detection of Covid-19 at the revised rate of ₹ 500/- per test without turning away any person seeking to undergo the test and that if it is detected that excess charge is being levied or if any private laboratory denies the testing at the rate fixed by the Government of Kerala, they shall be deemed to have committed offenses under the provisions of the Disaster Management Act, 2005, the Kerala Epidemic Diseases Ordinance, 2020 and other relevant provisions of law and action will be initiated against such laboratories accordingly. The petitioners are aggrieved by Exts.P10 and P11.

STATE'S DEFENCE

6. A statement has been filed on 07.05.2021 on behalf of the 1st respondent, as directed by this Court on 04.05.2021. It is stated that there are complaints that the RT-PCR test rates in the State is the highest in the country. Annexure I news report is produced to show that the rates in the States of Punjab are Rs.415/- and the rates in Maharashtra, Haryana, and Uttarakhand is Rs.500/-. Annexure-II news report is produced to show that the rates in Orissa are Rs.400/-. It is further stated that all laboratories except 10 laboratories have accepted the rates fixed by the Government. It is stated that the cost of the PCR kits and other

materials required for conducting the test has gone down considerably. Annexure III communication dated 01.07.2020 from the Secretary to Department of Health Research & Director General ICMR has been produced to show that there was a direction to finalise the rate for RT-PCR test by private laboratories. According to the statement, Annexure III required the States to finalise the rates of RT-PCR tests by private labs and it is pursuant thereto that Ext.P10 order has been issued. The statement also contains details of the rates for different tests prevailing during different periods and the costs of various types of kits that are to be used for conducting the tests. It is stated that the cost for conducting the test based on the costs of the inputs, for the period from December 2020 to January 2021, was between Rs.275/-to Rs.350/-, and hence the price fixed at Rs.500/- is reasonable. It is also stated that the rates arrived at by the 4th respondent for doing RT-PCR tests through static and mobile RT-PCR labs is Rs.448.20/-per test.

7. The statement also says that there are 10 static labs (private) across the State in the 3 Airports where the test is being conducted at the rate of Rs.448.20/- per test. The latest market rates that the 4th respondent had arrived at through competitive tender process excluding the HR and other overhead costs were Rs.135/- to Rs.240/- per test.

8. The 1st respondent has thereafter on 08.07.2021 filed a counter-affidavit, reiterating the contentions in the statement filed earlier. In addition to the contents of the statement, it is contended in the counter affidavit that the State is empowered to issue Ext.P10 by exercising the powers under the relevant provisions of the Disaster Management Act 2005, Section 2 of the Epidemic Diseases Act, 1897, Section 86 of the Travancore-Cochin Public Health Act, 1955, Section 81 of the Madras Public Health Act, 1939, Section 4 of the Kerala Epidemic Diseases Ordinance, 2020 and the executive powers vested in the Government under Article 162 of the Constitution of India, with relation to Entry 6 of List II of 7th Schedule of the Constitution of India dealing with public health and sanitation, hospitals and dispensaries. It is also submitted that the fundamental rights guaranteed under Articles 19 and 21 are subject to reasonable restrictions and there is no fundamental right to indulge in unchecked profiteering, particularly during pandemic times and that the individual fundamental rights should bow down to compelling public interests, in such health emergencies.

9. Heard Sri.P.Raveendran, learned Senior Advocate instructed by Sri.Paul Jacob on behalf of the petitioners, learned Advocate General on behalf of the State, Sri.M.Ajay, learned counsel on behalf of the 4th respondent KMSCL and Sri P.Vijayakumar, learned Assistant Solicitor General of India.

AN ATTEMPTED ADR THAT FAILED

10. During the hearing, this Court felt that if the 4th respondent can be persuaded to supply the materials which are required by the petitioners as a

temporary measure at the low rates at which they can procure, an economically viable solution can be arrived at. On that basis, an order was issued on 08.07.2021 directing respondents 1 and 4 to consider the proposition and submit before the Court about the possibility of the 4th respondent supplying the materials. Petitioners were also directed to supply the list of the materials that they would require for conducting the RT-PCR test to the 4th respondent and the approximate volumes that would be required so that the 4th respondent will be able to arrive at a competitive price. Thereafter, on 23.07.2021, this Court recorded the submission of the learned Advocate General that the Government has in principle agreed to the proposition that the 4th respondent can supply the materials as a temporary measure in the light of the situation created by the pandemic. The petitioners were permitted to place their orders before the 4th respondent for the supply of materials at the reduced costs and the 4th respondent was also directed to arrange for supply based on such orders. On 30.07.2021, when the cases were again taken up, it was submitted by the petitioners that they had given their requirements to the 2nd respondent. The learned counsel for the 4th respondent and the learned Advocate General submitted that they are yet to receive the requirements of the petitioners and hence they are not in a position to give a specific reply. The learned Senior Counsel appearing for the petitioners submitted that the route map which has been suggested by the Government would show that the process will take more than 30 days and there was no clarity regarding the price. This Court hence directed the petitioners to place their requirements immediately before the 4th respondent vide e-mail and also to forward a copy of the same to the Standing Counsel for the 4th respondent. It was also directed that the copy of the same should be submitted to the 1st respondent as well. The case was directed to be posted on 03.08.2021 for further orders.

11. On 04.08.2021, a statement has been filed by the Standing counsel for the 4th respondent as directed by this Court on 03.08.2021, wherein it is stated that on an analysis of requirements received from 22 Laboratories, it was found that some of them were brand-specific and some were run of the mill items and only 45 items out of the 115 different items demanded by different laboratories can be readily arranged to be supplied through rate contracts entered into by the KMSCL. It can be seen from the note attached to Annexure I statement that brand-specific PCR kits cannot be procured since they will not yield the desired cost advantage envisaged out of the bulk procurement through the 4th respondent KMSCL. It is also stated that the consumables of automated RNA extraction kits from nine different manufacturers have been requested and bulk procurement advantage will not be obtained if consumables are procured for different brands. It is also stated that most of the consumables for automated RNA extracting machines are proprietary and the 4th respondent will not be able to procure the consumables for such equipment.

12. Reading through the statement and notes and after hearing the counsel for the parties, it is evident that the suggestion made by this Court based on a

prima facie impression that a viable solution could be arrived at by directing procurement by the 4th respondent for supply to the petitioners, will not be feasible.

ARGUMENTS ON BEHALF OF THE PETITIONERS

13. The learned Senior Counsel appearing for the petitioners submits that going by Ext.P3 judgment, initially the direction was to conduct the test free of cost. In Ext.P4, the directions were modified and in direction No.3 in Ext.P4, the Hon'ble Supreme Court specifically said that private laboratories can continue to charge the test fee fixed by ICMR, for testing of Covid-19, from persons who can make the payment. According to the Senior Counsel, it is for the ICMR to fix the rates and ICMR had initially fixed the rate at ₹ 4,500/-. Later in Ext.P23, the ICMR directed the State Governments to arrive at the price after discussing with the private laboratories. It is on that basis Ext.P1 was issued. It is submitted that even though by Ext.P2 order the amount of ₹ 2,750/- in Ext.P1 was revised to ₹ 2,100/-, the petitioners had accepted the rate since it was felt reasonable. However, when Ext.P5 was issued, reducing the rate to ₹ 1,500/- without any discussion with the private laboratories, the petitioners had approached this Court which resulted in Ext.P6 judgment whereby the Government was directed to take a fresh decision after hearing. It is submitted that the Government accepted the decision of this Court and issued Ext.P7, which it is submitted, is issued after discussion with the private laboratories. It is submitted that Ext.P8 cost analysis carried out with the help of a Cost Accountant shows that an amount of ₹ 1,516/- would be the cost of conducting one test. It is submitted that even though the Government was fully aware of the direction of the Hon'ble Supreme Court that the private laboratories can continue charging at the rate fixed by the ICMR and the direction issued by the ICMR to the State Government to arrive at the price after discussing with the private laboratories and the further fact that in Ext.P6, this Court had interfered when a unilateral decision was taken to reduce the price and directed to fix the price after hearing the private laboratories also, they have proceeded to re-fix the price as per Ext.P10 unilaterally without any discussion with the stakeholders. The learned Senior Counsel pointed out that the 4th respondent is a Government agency and the price arrived at by them cannot be the basis, since they are making bulk purchases and necessarily they will be able to procure the materials at a very low price as against the price for which the private laboratories will be able to procure the materials for conducting the tests.

14. Regarding the contentions of the State Government, the learned counsel referred to paragraph 9 of the statement filed by the Government which seeks to justify the rates which have been fixed by the Government and submits that the direction of the ICMR to discuss with the private laboratories has conveniently not been mentioned. Paragraph 15 of the statement is also referred to, where the Government seeks to justify the reducing of the rates of the test, relying on the powers available under the Disaster Management Act, Epidemic Diseases Act,

1897, Kerala Epidemic Diseases Ordinance, 2020, and the executive power vested with the Government under Article 162 of the Constitution of India.

15. As the answer to the above contentions, the learned Senior Counsel submitted that Entry 34 in List III is the source of the power of the State to bring in legislation for "price control". Counsel referred to the Essential Commodities Act, 1955 (hereinafter referred to as EC Act), which is an enactment by the Parliament in the exercise of the power to bring out legislation for price control. Section 2A says that for the purpose of the EC Act, "essential commodity" means a commodity specified in the Schedule. Section 3 of the EC Act deals with price fixation for essential commodities. Item 1 in the Schedule of the Act is "Drugs" and the Explanation added below it says that "drugs" has the meaning assigned to it in clause(b) of Section 3 of the Drugs and Cosmetics Act, 1940. Section 3(b) of the Drugs and Cosmetics Act, 1940 defines 'drugs' to include "all substances intended to be used for or in the diagnosis" thus including diagnostic tools also. It is hence contended that price fixation of diagnostic tools is already covered under the Central enactment and the State Government cannot through an executive order fix the price and that too, in a case where specific directions were issued by the Hon'ble Supreme Court as well as the competent authority under the Central Government to fix the price after discussing with the private laboratories. It is further stated that Section 5 of the EC Act provides for delegation of the powers of the Union of India to the State Government. In exercise of the power so delegated, the State Government has enacted the Essential Articles Control Act, 1996. The definition of "Essential article" under Section 2(a) of the above said Act specifically excludes essential commodities as defined in the EC Act. That is to say "Essential article" as defined in the above Act does not include the Diagnostic tools; is the contention.

16. The learned Senior Counsel submitted that Exts.R1(a) to R1(e) produced along with the counter affidavit filed on behalf of the State cannot in any way be compared with Ext.P10. Ext.R1(a) is an order dated 20.04.2021 issued by the Director, Health and Family Welfare, Punjab, whereby it is directed that the private laboratories should not charge more than ₹ 450 for RT-PCR testing for Covid-19 inclusive of GST and taxes, documentation and reporting. It is seen from the order that the same has been issued invoking the power available under the Epidemic Diseases Act, 1897 and Covid-19 Regulations, 2020. In Ext.R1(b), which is an order issued by the Government of Haryana in the Department of Health and Family Welfare, the rate fixed for RT-PCR testing for Covid-19 cases is ₹ 450/-. However, the order would show that the order was issued after arriving at a consensus with the leading private laboratories. Ext.R1(c), is a news report stating that the rates in Maharashtra have been revised and that the cost is to be between ₹ 500/- and ₹ 800/-. Ext.R1(d) relates to the rate at Odisha, and it says that the rate at which the test is to be conducted by the private laboratories has been fixed at ₹ 400/-. The order says that the test is to be conducted under the supervision of the Regional Medical Research Centre, Bhubaneswar. The counsel further pointed out that the Government has on 27.05.2021 issued Ext.P24,

while the writ petition was pending, whereby the costs of 15 medical items were fixed under the provisions of Kerala Essential Articles Control Act, 1986. The items included in Ext.P24 are PPE kits, N95 masks, triple-layer masks, face shields, surgical gowns, examination gloves, sterile gloves, sanitizers, NRB masks, oxygen masks, flow meter with humidifier and fingertip pulse oximeters. It can be seen from Ext.P24 that even though the rates were fixed initially on 14.05.2021, the same was revised for the reason that the private hospitals and retailers who are doing small scale procurement may not be able to get the price advantage which the KMSCL would get, while procuring in large volumes based on competitive bidding. It can be seen that the rate of PPE kits initially fixed at the rate of ₹ 273/- was increased to ₹ 328/-. The learned counsel hence points out that Ext.P24 will clearly show that the reliance placed on the rates of the 4th respondent to arrive at ₹ 500/-for RT-PCR test was erroneous. The learned counsel hence submitted that Exts.P10 and P11 orders are liable to be set aside and the Government needs to issue fresh orders after hearing the petitioners also.

ARGUMENTS OF THE LEARNED ADVOCATE GENERAL

17. The learned Advocate General contended that it is well within the powers of the State to issue orders like Exts.P10 and P11. Relying on the decisions of the Hon'ble Supreme Court in *Union of India & Anr. v. Cynamide India Ltd. & Anr.* reported in [(1987) 2 SCC 720], *Welcom Hotel & Ors. v. State of Andhra Pradesh & Ors.* reported in [(1983) 4 SCC 575], and *Sai Bhaskar Iron Limited v. A.P.Electricity Regulatory Commission* reported in [(2016) 9 SCC 134], it is contended that price fixation/revision of the rates for RT-PCR test is a legislative function which excludes the application of the principles of natural justice and this Court may not exercise the jurisdiction under Article 226 in cases of this nature. It is further contended that Article 162 provides ample powers to the State in such matters. Section 72 of the Disaster Management Act, 2005, is relied upon to submit that the provisions of the said Act shall have an overriding effect over the provisions of any other law for the time being in force. It is also contended that power is available under the provisions of Epidemic Diseases Act, 1897, and the Public Health Ordinance, 2021, for the State to fix the rates for RT-PCR test.

18. Sri.M.Ajay, learned counsel appearing for the 4th respondent submitted that in the absence of legislation, the State can always exercise the executive power and hence Exts.P10 and P11 are well within the executive powers of the State.

ISSUES ARISING FOR CONSIDERATIONS

19. The issues that need to be decided in the above writ petitions are identified as follows:

(a) Is Ext.P10 issued by the Government a legislative process or an executive order?

(b) Is price fixation a legislative process and to what extent can the Court interfere?

(c) Should the State comply with the principles of natural justice while fixing the maximum rates at which the RT-PCR should be done in private laboratories?

(d) Can Ext.P10 be treated as an order issued by the State in exercise of the powers vested in it under the provisions of the Disaster Management Act 2005, Section 2 of the Epidemic Diseases Act, 1897, Section 86 of the Travancore-Cochin Public Health Act, 1955, Section 81 of the Madras Public Health Act, 1939, Section 4 of the Kerala Epidemic Diseases Ordinance, 2020 and the executive powers vested in the Government under Article 162 of the Constitution of India, with relation to Entry 6 of List II of 7th Schedule of the Constitution of India?

CONSIDERATION OF THE RIVAL CONTENTIONS

20. Article 246 of the Constitution of India empowers the Parliament and the State legislatures to make laws concerning the matters enumerated in the 7th Schedule. List 1 of the 7th Schedule enumerates the matters on which the Parliament can make laws. List 2 of the 7th Schedule enumerates the matters on which the State legislatures can make laws. List 3 of the 7th Schedule, called the Concurrent List, enumerates matters on which the Parliament, as well as State legislatures, can make laws. The Parliament can make laws on matters included in List 3, notwithstanding the power of the legislature to make laws concerning matters enumerated in List 2 of the 7th Schedule, while the State legislature can make laws concerning the matters enumerated in List 3 of the 7th Schedule, only subject to the power of the Parliament to make laws concerning the matters enumerated in List 1. Entry 34 in List 3 of the 7th Schedule is "price control". The Parliament enacted the EC Act, with the object to provide in the interest of the general public, for the control of the production, supply and distribution of, and trade and commerce, in certain commodities. Section 2A of the EC Act says that for the purpose of the EC Act "essential commodity" is a commodity specified in the Schedule to the EC Act. Section 2A(2) empowers the Government to amend the Schedule by the issuance of notification and publishing it in the Official Gazette. The relevant portions of Section 3 of the EC Act read thus:

"Section 3:- Powers to control production, supply, distribution, etc., of Essential Commodities

(1) If the Central Government is of the opinion that it is necessary or expedient so to do for maintaining or increasing supplies of any essential commodity or for securing their equitable distribution and availability at fair prices, or for securing any essential commodity for the Defence of India or the efficient conduct of military operations, it may, by order, provide for regulating or prohibiting the production, supply and distribution thereof and trade and commerce therein.

(2) Without prejudice to the generality of the powers conferred by sub-section (1) an order made thereunder may provide -

(a)	xxxx	xxxxx	xxxxx
(b)	xxxx	xxxxx	xxxxx

(c) for controlling the price at which essential commodity may be bought or sold;

xxxx	xxxxx	xxxxx	xxxxx
xxxxx"			

21. Serial No. 1 of the schedule to the EC Act is "drugs" and "drugs" has been assigned the meaning in clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940. Regarding control of prices of drugs, the Government has issued Drugs (Prices Control) Orders from time to time, in the exercise of the power vested in them under Section 3(2)(c) of the EC Act.

22. The power to issue such orders controlling the prices came up for consideration before the Hon'ble Supreme Court in *Cynamide* (supra). In paragraph 4 of the judgment, the Apex Court observed that "Price fixation is neither the function nor the forte of the court". It was held that the Court will only be concerned in appropriate proceedings to enquire into the question whether relevant considerations have gone in and irrelevant considerations kept out of the determination of the price. It was further held that the Court will not re-evaluate the considerations even if the prices are demonstrably injurious to some manufacturers or producers except to the extent of hostile discrimination. In paragraph 5 of the judgment, the Apex Court held that legislative action, plenary or subordinate, is not subject to rules of natural justice. However, the Court drew a distinction with regard to those subordinate legislations, where the Parliament may itself provide for a notice and for a hearing, in which case the substantial non-observance of the statutorily prescribed mode of observing natural justice may have the effect of invalidating the subordinate legislation. In paragraph 7 of the judgment, the Apex Court held that price fixation is more in the nature of a legislative activity than any other. The Court observed that with the proliferation of delegated legislation, there is a tendency for the line between legislation and administration to vanish into an illusion and chose to express the distinction between the two as "one between the general and the particular". That is, "A legislative act is the creation and promulgation of a general rule of conduct without reference to particular cases; an administrative act is the making and issue of a specific direction or the application of a general rule to a particular case in accordance with the requirements of policy". The Court proceeded to hold that a price fixation measure does not concern itself with the interests of an individual manufacturer or producer and is generally concerning a particular commodity or class of commodities or transactions. It was further observed that the right of the citizen to obtain essential articles at fair prices and the duty of the State to so provide them, are transformed into the power of the State to fix prices and the obligation of the producer to charge no more than the price fixed. In paragraph 27 of the judgment the Hon'ble Supreme Court held that nothing in the scheme of the Drugs (Prices Control) Order suggests that

price fixation under the Order is not a legislative activity, but a quasi-judicial activity which would attract the observance of the principles of natural justice. In paragraph 31 of the judgment, the Apex Court held that the price fixed by the Government may be questioned on the ground that the considerations stipulated by the order as relevant were not taken into account, or on any ground on which subordinate legislation may be questioned, such as, being contrary to constitutional or other statutory provisions or on the ground of a denial of the right guaranteed by Article 14, if it is arbitrary, that is, if either the guidelines prescribed for the determination are arbitrary or if, even though the guidelines are not arbitrary, the guidelines are worked in an arbitrary fashion.

23. In *Cynamide* (supra), the Hon'ble Supreme Court had relied on one of its earlier decisions in *Welcom Hotel* (supra). The challenge in *Welcom Hotel* (supra) was against a notification fixing the maximum price for seven items of food comprising the poor man's menu in Andhra Pradesh. The seven items were idli, vada, upma, sada dosa, puree, coffee, tea and rice plate. One of the contentions before the Court was that the price fixed as the maximum price was economically unprofitable and the same was arrived at without a scientific examination of the price of the inputs and overhead charges. A similar contention has been taken in the case on hand as well. For the above reason, it was contended that the price fixation suffers from the vice of arbitrariness. The Apex Court rejected the contention on the facts of the case, finding that the petitioners have not shown that in their overall turnover they have since the promulgation of the impugned orders suffered a loss. Another reason stated for rejecting the contention was the one laid down by a Constitution Bench of seven learned Judges of the Apex Court in *Prag Ice & Oil Mills v. Union of India* reported in [(1978) 3 SCC 459], that the mechanics of price fixation has to be left to the judgment of executive and unless it is patent that there is hostile discrimination against a class of operators, the processual basis of price fixation has to be accepted in the generality of cases as valid.

24. In *Sai Bhaskar* (supra), the Apex Court considered the scope of interference in judicial review in matters reserved for expert bodies. The Court held that the scope is limited and the court cannot substitute its opinion. The Hon'ble Supreme Court relied on the earlier decision of the Apex Court in *Bihar SEB v. Pulak Enterprises* reported in [(2009) 5 SCC 641] which in turn had considered the issue with reference to several earlier decisions including *Prag* (supra) and *Cynamide* (supra).

25. This Court does not have a second thought regarding the law laid down in the above-referred judgments. However, the case on hand stands on a different footing. This is not a case where the Government is relying on any legislation under Entry 34 of List III of Schedule 7 regarding price control. The State also does not have a case that the price fixation has been done in exercise of the powers available under the Essential Commodities Act. Instead, the contention is that the orders have been issued in exercise of power available under Section 2

of the Epidemic Diseases Act, 1897, Section 86 of the Travancore-Cochin Public Health Act, 1955, Section 81 of the Madras Public Health Act, 1939, relevant provisions of the Disaster Management Act, 2005, Section 4 of the Kerala Epidemic Diseases Ordinance, 2020 and the executive powers vested with the Government under Article 162 of the Constitution of India. Section 2 of the Epidemic Diseases Act, 1897 empowers the State to take special measures and prescribes regulations as to dangerous epidemic diseases. Section 2(1) provides that when State is satisfied that the State or any part thereof is threatened with an outbreak of any dangerous epidemic disease and the State thinks fit that the ordinary provisions of the law for the time being in force are not sufficient for the purpose, it may either by itself or through a person empowered to act, takes such measures and by putting notice, prescribe such temporary regulations to be observed by the public or by any person or class of persons, to prevent the outbreak of such disease or the spread thereof, and may determine in what manner and by whom such expenses incurred shall be defrayed. A reading of the Section shows that it does not deal with any price fixation or price control, but deals with actions to be taken for stopping the spread of any dangerous epidemic disease. It may be said that testing of persons to ascertain whether they are affected by the epidemic is also an ancillary step for stopping the spread of the disease. However, that would take in only imposing conditions as to compulsorily testing etc., but not price fixation of such tests conducted by private individuals or private laboratories. It is particularly so since the price control comes under a definite legislative entry and legislation is available in the form of the EC Act under which Drugs (Price Control) Orders are being issued from time to time for controlling the prices of drugs. Section 81 of the Madras Public Health Act empowers the Government to make rules for the treatment of persons affected by an epidemic, endemic, or other infectious diseases and for preventing the spread of such disease, and, the rules may declare by what authority or authorities the rules shall be enforced and executed. The above rule also does not deal with the issue of price fixation. The rule takes care of ensuring and enforcing vaccination and such subjects. Section 86 of the Travancore-Cochin Public Health Act is similarly worded as Section 81 of the Madras Public Health Act except for the further fact that the Kerala Act empowers the making of rules regarding leprosy as defined in Section 79 of the Act. Section 4(1) of the Kerala Epidemic Diseases Ordinance is similarly worded as Section 2(1) of the Epidemic Diseases Act, 1897, but specifically states that the person empowered for exercising powers under the Section is the District Collector. Section 4(2) of the Ordinance says that the Government may take measures or specify regulations to prohibit any usage or act which the Government considers sufficient to spread or transmit epidemic diseases from person to person in any gathering, etc., to inspect persons arriving in the State by air, rail, road, sea or any other means or in quarantine or in isolation, etc., to seal State Borders for such periods as may be deemed necessary, to impose restrictions on the operation of public and private transport and similar matters. The Section does not speak anything about price control/price fixation of RT-PCR tests. The Government has thereafter

amended the Epidemic Diseases Act, 1897 by the Epidemic Diseases (Amendment) Act, 2020, providing for additional provisions to control any acts of violence or similar actions against healthcare service personnel and property in clinical establishments, mobile medical units, etc.

26. The Disaster Management Act, 2005 (DM Act, for short) was enacted to provide for effective management of disasters and matters connected therewith. The said Act deals with the establishment of disaster management authorities under the National, State, and District levels and regarding measures by the Government for disaster management. The statement filed on behalf of the State did not refer to the exact provision under the Act which gives power to the State to fix the rates for RT-PCR tests. Sections 20, 24, and 65 of the Act are relied upon to support the arguments on behalf of the State. Section 20 of the DM Act provides for the constitution of a State Executive Committee for combating a disaster or a threatened disaster and does not deal with price fixation/control. Section 24 of the DM Act spells out the powers and functions of the State Executive Committee. None of the functions (a) to (l) mentioned in the Section deals with price control. Section 24(d) alone which says "provide shelter, food, drinking water, essential provisions, healthcare, and services in accordance with the standards laid down by the National Authority and State Authority", refers to healthcare. However, a reading of the provision along with the other functions enumerated shows that the legislature was not contemplating a disaster in the form of a pandemic like Covid-19, when it enacted the DM Act. It can be seen that the Act covers all disasters and does not specifically deal with a disease caused by an epidemic or an endemic or a pandemic like Covid-19. The responsibilities of the State is contained in Section 38 of the Disaster Management Act, which does not speak of price control. The responsibilities of Departments of the State Government are stated in Section 39 which deals with providing healthcare and services in an affected area. Apart from that, there are no other provisions in the Act that deals with either fixing of rates at which a private laboratory should perform RT-PCR test or for taking action against such laboratories who refused to perform the tests at the price so fixed by the State.

27. The only other power which is available to the Government is the executive power vested under Article 162 of the Constitution of India. Article 162 reads thus;

"162. Extent of executive power of State.- Subject to the provisions of this Constitution, the executive power of a State shall extend to the matters with respect to which the Legislature of the State has power to make laws:

Provided that in any matter with respect to which the Legislature of a State and Parliament have power to make laws, the executive power of the State shall be subject to, and limited by, the executive power expressly conferred by the Constitution or by any law made by Parliament upon the Union or authorities thereof."

It can be seen that the the executive power of the State shall be subject to, and limited by, the executive power expressly conferred by the Constitution or by any law made by the Parliament upon the Union or authorities thereof.

28. In the case on hand, the contention advanced by the Senior Counsel for the petitioners that the word 'drugs' as defined in the Drugs and Cosmetics Act, 1940, includes substances intended to be used for or in the diagnosis, which will take in diagnostic tools is well-founded. This question had come up for consideration before the Hon'ble Supreme Court in *Chimanlal Jagjivan Das Sheth v. State of Maharashtra*, reported in [AIR 1963 SC 665]. In paragraph 3 of the judgment, the Apex Court held that the definition of "drugs" is comprehensive enough to take in not only medicines but also substances intended to be used for or in the treatment of diseases of human beings or animals. It was held that the artificial definition introduces a distinction between medicines and substances which are not medicines strictly so-called. It was further held that the appropriate meaning of the expression "substances" in the Section is "things" and it cannot be disputed that absorbent cotton wool, roller bandages, and gauze are "substances" within the meaning of the said expression. Since "drugs" is an essential commodity under the EC Act, it was possible to make a law to control the price of the RT-PCR test by the issuance of a Drug (Price Control) Order or such other piece of legislation under Section 3(2)(c) of the EC Act. However, there is no such legislation in place. The State on the other hand relies on Entry 6 in List II of Seventh Schedule of the Constitution of India, apparently to say that the power to legislate is available with the State. Entry 6 reads as "Public health and sanitation; hospitals and dispensaries". If the widest interpretation is to be given to Entry 6 to include the control of the price of laboratory tests, it can only result in a transgression into the area already occupied by Section 3(2)(c) of the EC Act. I am of the opinion that such an interpretation is not warranted. Since there is no case that the Central Government has issued any Drugs (Price Control) Orders to cover the rates of RT-PCR tests, the field of legislation was very much open to the State and there would not have been any case of repugnancy.

CONCLUSIONS:

29. Based on the detailed considerations above, I am of the opinion that none of the statutory provisions relied on by the State authorises them to issue an order controlling the rates at which the private laboratories should carry out the RT-PCR test. I am of the opinion that RT-PCR test also stands included within the meaning of the word "drugs" going by the test laid down by the Hon'ble Supreme Court in *Chimanlal* (supra) and hence an "essential commodity". Ext.P10 cannot also be treated as an order issued by the State in exercise of the powers vested in it under the provisions of the Disaster Management Act 2005, Section 2 of the Epidemic Diseases Act, 1897, Section 86 of the Travancore-Cochin Public Health Act, 1955, Section 81 of the Madras Public Health Act, 1939, Section 4 of the Kerala Epidemic Diseases Ordinance, 2020 and the executive powers vested in

the Government under Article 162 of the Constitution of India, with relation to Entry 6 of List II of 7th Schedule of the Constitution of India. Ext.P10 issued by the Government can hence only be treated as an executive order and cannot be treated as a part of a legislative process and it is open to judicial review on the grounds available for judicial review against executive/administrative orders. The price fixation regarding the RT-PCR test was undertaken by the State Government only after the ICMR had directed the State Governments to arrive at the rates for the RT-PCR tests to be charged by the private laboratories after discussing with them, which in turn was after the orders issued by the Hon'ble Supreme Court permitting the private laboratories to charge at the rates fixed by the ICMR. Whether the ICMR has been statutorily empowered to issue orders fixing the maximum price at which a test necessary for diagnosis is to be conducted was not gone into by the Hon'ble Supreme Court, apparently for the fact that the situation required immediate action. The ICMR in turn decided to relegate the price fixation to the State level with a rider that price will be fixed after discussions. When the price was fixed without any discussion, this Court intervened and directed the Government to fix the price after discussing with the private laboratories. It is thereafter that the price of ₹ 1,700/- for RT-PCR test was arrived at. The State also does not have a case till the issuance of the order fixing the price of ₹ 1,700/-, that they had all the powers to fix the price without any discussion with private laboratories and without hearing them. The contention is taken in answer to the claim in this writ petition that the State does not have the power to fix the price in the manner in which it was done. I am hence of the opinion that, when the price is fixed, as a result of the directions issued by the ICMR pursuant to a judgment of the Hon'ble Supreme Court, necessarily, the State was obliged to discuss the matter with private laboratories. It is not as if the State is not aware of this requirement, since they had held discussions on 19.06.2020 and 28.01.2021 as directed by the ICMR and by this Court respectively. In the above circumstances, Ext.P10 order issued without conducting a discussion with the private laboratories and that too in a matter in which they are seriously affected (reduction of the price for RT-PCR test from ₹ 1,700 to ₹ 500) cannot be legally sustained. I am hence of the opinion that Ext.P10 is liable to be set aside and the State Government should take a fresh decision regarding the rate at which the RT-PCR should be conducted after discussing the issue with the private laboratories. The above requirement is all the more justified having regard to the fact that the only material on which the State Government had relied on to bring down the rate to ₹ 500/- was a report from the 4th respondent regarding the cost of inputs required for conducting the test. Admittedly, the 4th respondent is making bulk purchases and has the benefit of very low prices which will not be available to the private laboratories. The 4th respondent has also stated before the Court that even if they were to procure the materials for supply to the private laboratories as a temporary measure, they will not be able to procure all the materials, that the private laboratories would require. It can thus be seen that the cost at which the private laboratories are carrying on the tests cannot be determined solely based on the

report from the 4th respondent regarding the rate at which the test can be conducted. The above defects can be set right if the petitioners are afforded a chance to put forward their difficulties and the same is also considered by the Government before fixing the rates for the RT-PCR test. The reliance placed on the cost of RT-PCR test in the other States, is also not a reasonable yardstick, since there is no material either before the Government or before the Court to ascertain how the prices were arrived at in the said States.

30. Having said so, the fact remains that the tests are at present being conducted following the price fixed as per Ext.P10. According to the petitioners, they are suffering huge losses as a result and they cannot continue for a long and they will have to close down their laboratories to avoid prosecution. At the same time, it would not be proper to set aside Ext.P10 and permit the petitioners to continue to charge ₹ 1700/- which they were charging earlier with immediate effect. The interest of justice requires that the State Government decides the matter after hearing the petitioners or their representatives at the earliest, at any rate, within three weeks from the date of receipt of a copy of this judgment.

RELIEFS:

31. In the result, Exts.P10 and P11 are set aside. The 1st respondent is directed to take a fresh decision regarding the rate at which the RT-PCR tests shall be conducted by the private laboratories in the State after discussing with the owners or representative of such private laboratories, within three weeks from the date of receipt of a copy of this judgment. To facilitate the process of discussion and taking a decision, the order setting aside Exts.P10 and P11 is kept in abeyance for one month. However, the above direction to keep in abeyance Ext.P11 should not be understood to be a permission to take coercive action against the petitioners or similarly situated persons.

The writ petitions are disposed of as above.