

IN THE HIGH COURT OF KERALA AT ERNAKULAM
PRESENT
THE HONOURABLE MR. JUSTICE HARISANKAR V. MENON

Wednesday, the 15th day of July 2026 / 24th Ashadha, 1948
WP(C) NO. 18999 OF 2022(Y)

PETITIONER:

XXXXXXXXXX AGED 62 YEARS RESIDENT OF ERNAKULAM, PIN - 682301

RESPONDENTS:

1. UNION OF INDIA REPRESENTED BY SECRETARY, MINISTRY OF HEALTH AND FAMILY WELFARE, GOVERNMENT OF INDIA, ROOM NO. 348; 'A' WING, NIRMAL BHAVAN, NEW DELHI-110 011 PIN - 110 011
2. SECRETARY, DEPARTMENT OF PHARMACEUTICALS MINISTRY OF CHEMICALS AND FERTILIZERS, GOVERNMENT OF INDIA, 236A, A- WING, 2ND FLOOR, SHASTRI BHAVAN, DR. RAJENDRA PRASAD ROAD, NEW DELHI , PIN - 110 001
3. SECRETARY, DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE (DPIIT) UDYOG BHAVAN, NEW DELHI , PIN - 110 011
4. SECRETARY, MINISTRY OF WOMEN AND CHILD DEVELOPMENT, SHASTRI BHAVAN, DR. RAJENDRA PRASAD ROAD, NEW DELHI PIN - 110 001
5. CONTROLLER GENERAL OF PATENTS, DESIGNS AND TRADE MARKS, PATENT OFFICE KOLKATA, BOUDHIK SAMPADE BHAVAN, CP-2 SECTOR V, SALT LAKE CITY, KOLKATA, PIN - 700 091
6. INDIAN COUNCIL OF MEDICAL RESEARCH REPRESENTED BY DIRECTOR-GENERAL, ANSARI NAGAR, NEW DELHI PIN - 110 029
7. ADDL.R7. RAHUL BAJAJ 001, SARVAPRIYA VIHAR APARTMENTS, NEW DELHI - 110 016.(ADDITIONAL R7 IS IMPEADED AS PER ORDER DATED 02.09.2022 IN I.A.1/2022 IN WP(C)18999/2022).
8. ADDL.R8. ELI LILLY COMPANY (INDIA) PVT.LTD. PLOT# 92, SECTOR 32, INSTITUTIONAL AREA, GURGAON 122 001, HARYANA, INDIA [IS SUO MOTU IMPEADED AS PER ORDER DATED 15.03.2023 IN WP(C)18999/2022.]
9. ADDL.R9. NOVARTIS A G LICHTRASSE 35, CH - 4056 BASEL, SWITZERLAND. (IS SUO MOTU IMPEADED AS PER ORDER DATED 16.06.2023 IN WPC 18999/2022).
10. ADDL.R10. M.RADHAKRISHNAN S/O.KRISHNAMENON, AGED 74 YEARS, RESIDING AT PRA 45A, MANDANATHU, PALLIPARAMBUKAVU ROAD, TRIPUNITHURA, ERNAKULAM-682 301 [ADDL.R10 IS IMPEADED AS PER ORDER DATED 19.10.2023 IN I.A.3/2023 IN WP(C)18999/2022].
11. ADDL. R11. NATIONAL CANCER INSTITUTE, AIIMS, JHAJJAR, BADSA, JHAJJAR, HARYANA, PIN-124105.
12. ADDL. R12. CHITTARANJAN NATIONAL CANCER INSTITUTE, SHYAMA PRASAD MUKHERJEE ROAD, BAKUL BAGAN, BHOWANIPORE, KOLKATA, WEST BENGAL, PIN-700 026
13. ADDL. R13. REGIONAL CANCER CENTRE, THIRUVANANTHAPURAM, KUMARAPURAM ROAD, MEDICAL COLLEGE CAMPUS, CHALAKKUZHI, PIN-695 011
14. ADDL. R14. THE DRUG CONTROLLER GENERAL OF INDIA, FDA BHAVAN, ITO, KOTLA ROAD, NEW DELHI, PIN-110 002 (ADDL. R11 TO R14 ARE SUO MOTU IMPEADED AS PER ORDER DATED 15.07.2026 IN WPC 18999/2022)

Writ petition (civil) praying inter alia that in the circumstances stated in the affidavit filed along with the WP(C) the High Court be pleased to direct the 3rd respondent to consider and pass orders on Ext. P25 representation within a timeframe to be fixed by this Hon'ble Court.

This petition coming on for orders upon perusing the petition and the affidavit filed in support of WP(C) and upon hearing the arguments of SMT. MAITREYI SACHIDANANDA HEGDE Advocates for the petitioner, DEPUTY SOLICITOR GENERAL OF INDIA for R1, R2 & R4, SRI. KRISHNA T.C for R3 & R5, M/S. ARUN KUMAR P., THIYYANNOOR RAMAKRISHNAN, AMBIKA RADHAKRISHNAN, KAVYA SURESH Advocates for R8, M/S. ABRAHAM JOSEPH MARKOS, V. ABRAHAM MARKOS, ISAAC THOMAS, P.G.CHANDAPILLAI ABRAHAM, ALEXANDER JOSEPH MARKOS, SHARAD JOSEPH KODANTHARA, AIBEL MATHEW SIBY, JOHN VITHAYATHIL Advocates for R9, M/S. K.JAJU BABU (SR.), BRIJESH MOHAN, M.U.VIJAYALAKSHMI for Advocates for ADDL. R10 and ADDL. SOLICITOR GENERAL OF INDIA for ADDL. R14 the court passed the following:



1

W.P. (C) No.18999 of 2022

WEDNESDAY, THE 15TH DAY OF JULY 2026WP(C) No. 18999 of 2022

XXXXX XXXXX

VS

UNION OF INDIA & OTHERS

ADVS FOR PETITIONER/S:

SMT.MAITREYI SACHIDANANDA HEGDE

ADVS FOR RESPONDENT/S:

O.M.SHALINA, DEPUTY SOLICITOR GENERAL OF INDIA,
SRI.ABRAHAM JOSEPH MARKOS, M/S.JNPS LEGAL ASSOCIATES,
SRI.T.C.KRISHNA, SENIOR PANEL COUNSEL,
SRI.ARUN KUMAR.P,
SMT.M.U.VIJAYALAKSHMI,
SRI.V.ABRAHAM MARKOS,
SRI.ISAAC THOMAS,
SRI.P.G.CHANDAPILLAI ABRAHAM,
SRI.ALEXANDER JOSEPH MARKOS,
SRI.SHARAD JOSEPH KODANTHARA,
SRI.AIBEL MATHEW SIBY,
SRI.JOHN VITHAYATHIL,
SRI.THIYYANNOOR RAMAKRISHNAN,
SMT.AMBIKA RADHAKRISHNAN,
SMT.KAVYA SURESH,
SRI.K.JAJU BABU (SR.),
SRI.BRIJESH MOHAN



W.P. (C) No.18999 of 2022

HARISANKAR V. MENON, J.**W.P. (C) No.18999 of 2022****Dated this the 15th day of July, 2026****ORDER**

This writ petition was originally instituted by a patient, who was diagnosed to have breast cancer- HR Positive HER2-Negative Metastatic Breast Cancer. During the pendency of the writ petition, the petitioner passed away. Thereafter, taking note of the submissions made by Smt.Maitreyi Sachidananda Hegde, the learned counsel for the petitioner, who was originally appearing for the deceased petitioner, on 16.09.2022, this Court decided to continue with the writ petition as regards the issue of exorbitant pricing of life saving patented medicines. The Registry was also directed to substitute the petitioner's name as "In Re Exorbitant Pricing of Life Saving Patented Medicines". It is in such circumstances that this writ petition has been posted before this Court.

2. Smt.Maitreyi Sachidananda Hegde, learned *Amicus Curiae*, appointed by this Court, as above, made extensive

W.P. (C) No.18999 of 2022

submissions. She made reference to the Patents Act, 1970 (hereinafter referred to as the 'Act'), more specifically the provisions of Section 100 as well as Section 92. According to her, the medicine for the treatment of the aforementioned disease is 'Ribociclib', which is being manufactured by Novartis AG. She would submit that the afore medicine is a costly one, requiring a monthly expenditure of around Rs.58,000/- or more, when the writ petition was presented. According to her, insofar as the medicine is a costly one, the Government needs to interfere under Section 100 of the Act, by using the afore patent for the 'purposes of the Government'. In the alternative, she relies on the provisions of Section 92 of the Act, and states that the Government is required to issue a notification as specified under Section 92 of the Act, taking note of the afore aspect.

3. However, it is pointed out on behalf of the respondents by Sri.S.Sreekumar, the learned Senior counsel for the 8th respondent, as well as Sri.Joseph Kodianthara, learned Senior counsel, and Sri.Hemant Singh, learned counsel for the 9th respondent, that there is no requirement for invoking the provisions of Sections 92 and 100 for more than one reason.

W.P. (C) No.18999 of 2022

According to them, in the counter affidavit dated 01.11.2022 filed by the 1st respondent, Exhibit R1(b) proceedings dated 07.10.2022, have been relied upon, as per which the Government has found that there was no necessity for invoking Sections 92 and 100 of the Act. Secondly, they would point out that even from the afore statement, another medicine- 'Palbociclib', which was originally being manufactured on the basis of a patent by the company M/s.Pfizer Products India Pvt. Ltd., is out of patent, on account of which the afore medicine is being manufactured by various companies in India and available at a cheaper, affordable prize.

4. In view of the afore, the question is as to whether the second medicine -'Palbociclib'- is a medicine that can be used for treating the situation noticed in this writ petition, as above. If that be the case, *prima facie*, I am of the opinion that there is no requirement for making reference to the provisions of Sections 92 or 100, since they would be purely academic in nature.

5. However, Smt.Maitreyi, would emphatically point out that the Union of India has informed this Court by producing

W.P. (C) No.18999 of 2022

Ext.R1(b), without carrying out an extensive study in the matter. According to her, the molecules contained in these two medicines are different, insofar as the clinical profile as well as the toxicological profile are different, on account of which they are not interchangeable. However, this submission has been refuted by Sri.Hemant Singh, learned Senior counsel for the 9th respondent stating that 'Rabociclib' as well as 'Palbociclib' are only two different molecules, used for treating the same kind of breast cancer.

6. In view of the afore submissions, I am of the opinion that the views of the National Cancer Institute, Jhajjar, as well as Chittaranjan National Cancer Institute, Kolkata, and that of the Regional Cancer Centre, Thiruvananthapuram, as also the Drug Controller General of India, requires to be obtained in the matter.

7. In such circumstances, National Cancer Institute, AIIMS, Jhajjar, Badsa, Jhajjar, Haryana, PIN-124105; Chittaranjan National Cancer Institute, Shyama Prasad Mukherjee Road, Bakul Bagan, Bhowanipore, Kolkata, West-Bengal, PIN-700026; Regional Cancer Centre,

W.P. (C) No.18999 of 2022

Thiruvananthapuram, Kumarapuram Road, Medical College Campus, Chalakkuzhi, PIN-695011, and the Drug Controller General of India, FDA Bhavan, ITO, Kotla Road, New Delhi, PIN-110002; are *suo motu* impleaded as additional respondents 11, 12, 13, and 14. Registry to carry out necessary changes in the cause title.

8. Issue notice by speed post to additional respondents 11, 12 and 13. The learned Additional Solicitor General of India, takes notice for the additional 14th respondent.

9. There will be a direction to the additional respondents 11 to 14, impleaded as above, to take note of the afore and file a report before this Court, as regards the points noticed as above.

Post on 21.08.2026.

Sd/-
HARISANKAR V. MENON
JUDGE

Skk

APPENDIX OF WP(C) 18999/2022

Exhibit R1(b)

**True copy of the order No. P-24013(14)/1/2022-/PR-III
dated 07.10.2022**

