CNR : KLHC010381092022

IN THE HIGH COURT OF KERALA AT ERNAKULAM

PRESENT

THE HONOURABLE MR. JUSTICE HARISANKAR V. MENON

MONDAY, THE 28TH DAY OF SEPTEMBER 2026 / 6TH ASWINA, 1948

WP(C) NO. 18999 OF 2022

PETITIONER:

***IN RE* EXORBITANT PRICING OF LIFE SAVING PATENTED MEDICINES.**

(SUBSTITUTED AS PER ORDER DATED 16.09.2022)

BY SMT.MAITREYI SACHIDANANDA HEGDE, *AMICUS CURIAE*

RESPONDENTS:

1 UNION OF INDIA,
REPRESENTED BY SECRETARY, MINISTRY OF HEALTH
AND FAMILY WELFARE, GOVERNMENT OF INDIA, ROOM NO.348;
'A' WING, NIRMAN BHAVAN, NEW DELHI-110011.

2 SECRETARY, DEPARTMENT OF PHARMACEUTICALS,
MINISTRY OF CHEMICALS AND FERTILIZERS, GOVERNMENT OF INDIA,
236A, A- WING, 2ND FLOOR, SHASTRI BHAWAN,
DR.RAJENDRA PRASAD ROAD, NEW DELHI, PIN – 110001.

3 SECRETARY, DEPARTMENT FOR PROMOTION OF INDUSTRY
AND INTERNAL TRADE (DPIIT),
UDYOG BHAWAN, NEW DELHI, PIN – 110011.

4 SECRETARY, MINISTRY OF WOMEN AND CHILD DEVELOPMENT,
SHASTRI BHAWAN, DR. RAJENDRA PRASAD ROAD, NEW DELHI,
PIN – 110001.

5 CONTROLLER GENERAL OF PATENTS,
DESIGNS AND TRADE MARKS, PATENT OFFICE KOLKATA,
BOUDHIK SAMPADA BHAWAN, CP-2 SECTOR V, SALT LAKE CITY,
KOLKATA, PIN – 700091.

6 INDIAN COUNCIL OF MEDICAL RESEARCH
REPRESENTED BY DIRECTOR-GENERAL,
ANSARI NAGAR, NEW DELHI, PIN – 110029.

ADDL.R7 RAHUL BAJAJ, 001, SARVAPRIYA VIHAR APARTMENTS,
NEW DELHI - 110016.

(ADDITIONAL R7 IS IMPLEADED AS PER ORDER DATED 02.09.2022 IN I.A.NO.1/2022 IN WP(C) NO.18999/2022).

ADDL.R8 ELI LILLY COMPANY (INDIA) PVT. LTD.,
PLOT# 92, SECTOR 32, INSTITUTIONAL AREA, GURGAON - 122 001,
HARYANA, INDIA

[IS SUO MOTU IMPLEADED AS PER ORDER DATED 15.03.2023 IN WP(C)NO.18999/2022]

ADDL.R9 NOVARTIS A G., LICHTRASSE 35, CH - 4056 BASEL,
SWITZERLAND.

(IS SUO MOTU IMPLEADED AS PER ORDER DATED 16.06.2023 IN WP(C) No.18999/2022).

ADDL.R10 M.RADHAKRISHNAN, S/O.KRISHNAMENON, AGED 74 YEARS,
RESIDING AT PRA 45A, MANDANATHU, PALLIPARAMBUKAVU ROAD,
TRIPUNITHURA, ERNAKULAM-682301.

[ADDL.R10 IS IMPLEADED AS PER ORDER DATED 19.10.2023 IN I.A.NO.3/2023 IN WP(C)NO.18999/2022]

ADDL.R11 NATIONAL CANCER INSTITUTE, AIIMS, JHAJJAR, BADSA,
JHAJJAR, HARYANA, PIN-124105.

ADDL.R12 CHITTARANJAN NATIONAL CANCER INSTITUTE,
SHYAMA PRASAD MUKHERJEE ROAD, BAKUL BAGAN,
BHOWANIPORE, KOLKATA, WEST BENGAL, PIN-700 026.

ADDL.R13 REGIONAL CANCER CENTRE,
THIRUVANANTHAPURAM, KUMARAPURAM ROAD,
MEDICAL COLLEGE CAMPUS, CHALAKKUZHI, PIN-695 011.

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 IMPLEADED AS PER ORDER DATED 15.07.2026 IN WP(C) NO.18999/2022]

ADDL.R15 MAJIDA A.M., AGE 49, W/O. ADV. KHALEEMUDHEEN, RESIDING AT PADINHARAKAM ENNA KOLLANAKAM, NEAR T I UP SCHOOL, PONNANI NAGRAM, PONNANI, MALAPPURAM, KERALA- 679583.

[ADDL.R15 IS IMPLEADED AS PER ORDER DATED 21.08.2026 IN I.A.NO.1/26 IN WP(C) NO.18999/22]

BY ADVS.
O.M.SHALINA, DEPUTY SOLICITOR GENERAL OF INDIA
SRI.P.SREEKUMAR, ASGI
SRI.T.C.KRISHNA, SENIOR PANEL COUNSEL
M/S.JNPS LEGAL ASSOCIATES
SRI.ARUN KUMAR.P
SRI.ABRAHAM JOSEPH MARKOS
SRI.NAVANEETH GOPAN
SRI.AMAL PARTHASARADHY, CGC
SRI.ATHUL SHAJI, SC, REGIONAL CANCER CENTRE (RCC)
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.ASHISH ANTONY FRANCIS
SMT.OLIVIA LEELA JACOB
SRI.GOPAKUMAR K.M.
SRI.G.SHRIKUMAR, SENIOR COUNSEL
SRI.PRAVEEN ANAND
SRI.JOSEPH KODIANTHARA, SENIOR COUNSEL
SRI.HEMANTH SINGH
SRI.T.A.SHAJI, SENIOR COUNSEL
SRI.ARJUN VENUGOPAL, CGC
SRI.RAHUL BAJAJ

THIS WRIT PETITION (CIVIL) HAVING BEEN FINALLY HEARD ON 16.09.2026, THE COURT ON 28.09.2026 DELIVERED THE FOLLOWING:

"C.R."

JUDGMENT

The captioned writ petition was initially filed by a retired Bank employee, stated to have been receiving a monthly pension of Rs.28,400/-. Her husband is also a retired Bank employee, receiving Rs.46,000/- as monthly pension. She was diagnosed with HR+/HER2-Metastatic Breast Cancer being treated with 'targeted therapy' – CDK 4/6 inhibitors. The medicine "Ribociclib" is stated to be one among them. The said medicine is stated to block proteins called cyclin-dependent kinases 4/6 and thereby slow the Cancer's growth. This medicine is stated to be a costly one, costing about Rs.58,140/- for 21 days (three tablets per day). It is further stated that there are three major types of Breast Cancer, and treatment and medicines differ for each category. The major types are stated to be:

i. Invasive Breast Cancer
ii. Non-invasive Breast Cancer
iii. Cancerous Phyllodes Tumors.

Invasive Breast Cancer is again stated to be classified into four

categories as under:

i. HR+/HER2 – ("Luminal A")
ii. HR-/HER2- ("Triple Negative")
iii. HR+/HER2+ ("Luminal B")
iv. HR-/HER2+("HER2-enriched")

2. The petitioner is stated to be suffering from the first type - Luminal A HR+/HER2-. The petitioner contends that the financial assistance from the part of the Government for the treatment of Breast Cancer is minimal, and that steps are required to be taken for reducing the price of such medicines. Reference is made to the statutory provisions under the Patents Act, 1970 (hereinafter referred to as the 'Act') to contend that the Government is to intervene with reference to the provisions under Section 92/100, since on account of the grant of patent to the medicine, the same is exorbitantly costly, thereby affecting the life of patients like the petitioner. In such circumstances, the petitioner has instituted the captioned writ petition on 02.06.2022, seeking the following reliefs:

"i. To declare that the concerned among the respondent nos. 1 to 3 is duty bound to take steps either under

Section 92 or under Section 100 of the Patents Act, 1970 for Ribociclib and ensure availability of the same at a reasonably affordable price;

ii. To issue a writ of mandamus directing the concerned among the respondent nos.1 to 3 to take steps either under Section 92 or under Section 100 of the Patents Act, 1970 for Ribociclib and ensure availability and access of the same at a reasonably affordable price;

iii. To issue a writ of mandamus directing the first respondent to for a scheme to provide treatment for HER2-Negative Metastatic Breast Cancer patients including the petitioner, to provide Ribociclib at free of cost as part of National Cancer Control Programme;

v. To issue a writ of mandamus directing the 6th respondent to maintain the data with respect to each category of Breast Cancer cases registered each year in India and publish the same in the official website;"

(SIC)

3. While the writ petition was pending, the petitioner succumbed to her illness. Taking note of the afore as well as the submissions made by the learned counsel for the petitioner, this Court issued the following order on 16.09.2022:

"Learned Counsel for the petitioner reports that the petitioner has succumbed to her illness and submits that

> the noble cause espoused by the petitioner should not go in vain.
>
> I am also of the considered opinion that the unfortunate death should not result in the cause espoused through this writ petition being rendered infructuous. Therefore, this writ petition shall continue on the board of this Court, as a matter in which this Court has taken *suo motu* cognizance on the issue of exorbitant pricing of life saving patented medicines.
>
> Adv.Maitreyi Sachidananda Hegde is appointed as Amicus Curiae to assist the Court.
>
> Registry is directed to substitute the petitioner's name as '*In Re* Exorbitant Pricing of Life Saving Patented Medicines'."

4. Pending the writ petition, additional respondents 7, 10 and 15 were also permitted to be impleaded pursuant to the orders dated 02.09.2022, 19.10.2023, and 21.08.2026, respectively. They have joined the writ petition seeking to support the prayers raised in the writ petition noticed earlier.

5. On 07.02.2023, this Court, noticing the prayers made and the fact that the patented companies engaged in the manufacture of medicines involved in this case were not made

parties, was of the opinion that those companies are proper and necessary parties in the writ petition, and directed the Central Government Counsel to provide the address of the companies. Pursuant to the said direction, two companies stated to be engaged in the manufacture of such medicines were impleaded as additional respondents 8 and 9 pursuant to orders dated 15.03.2023 and 16.06.2023.

6. Separate counter affidavits have also been filed by respondents 1, 2, 3, 5, 8, 9 and 14. In the counter affidavit filed by the 1st respondent, it is pointed out that another medicine, "Palbociclib," which is stated to have been originally manufactured on the basis of a patent by another company, M/s.Pfizer Products India Pvt. Ltd. is already out of the patent, on account of which the said medicine is available at a lower and affordable price, adding that this medicine can also be used for the treatment of the particular type of cancer like "Ribociclib". In other words, it was pointed out that the afore two medicines are interchangeable.

7. In view of the afore, pursuant to the order dated 15.07.2026, the National Cancer Institute, Chittaranjan National Cancer Institute, Regional Cancer Centre (RCC) and Drug Controller General of India were also *suo motu* impleaded as additional respondents 11 to 14.

8. I have heard Smt.Maitreyi Sachidananda Hegde, the learned Amicus Curiae, Sri.P.Sreekumar, the learned Additional Solicitor General of India (ASGI) for respondents 1, 11 and 14, Smt.O.M.Shalina, the learned Deputy Solicitor General of India for the 4th respondent, Sri.T.C.Krishna, the learned Senior Panel Counsel for respondents 3 and 5, Sri.G.Shrikumar, the learned Senior Counsel instructed by Sri.P.Arun Kumar and Sri.Praveen Anand, the learned counsel for the 8th respondent, Sri.Joseph Kodianthara, the learned Senior Counsel instructed by Sri.John Vithayathil and Sri.Hemanth Singh, the learned counsel for the 9th respondent, Sri.T.A.Shaji, the learned Senior Counsel instructed by Sri.Atul Shaji, the learned Standing Counsel for RCC, as well as Sri.K.M.Gopakumar, the learned counsel for

respondents 10 and 15, extensively.

9. Smt.Maitreyi, the learned *Amicus Curiae*, would submit that:

i. Breast Cancer is one among the leading types of Cancer on account of which many patients die. She pointed out that every three minutes a woman is diagnosed with Breast Cancer in India, and in every six minutes one such woman dies. She pointed out that almost 80,000 patients diagnosed with Breast Cancer died during 2024. She further argued that treatment for cancer is a costly one adding that around 36% of the expenses would be the cost of medicine.

ii. She referred to the 139th report on "Cancer Care Plan and Management: Prevention, Diagnosis, Research and Affordability of Cancer Treatment" wherein, at paragraph 4.9.4, the Committee, having noticed that almost 40% of cancer hospitalisation cases are being financed through borrowings, sale of assets, etc., on account of which there is a gap in affordability, opined that "there is a strong need to make cancer care affordable through suitable interventions from both Government and private sectors".

iii. She referred to Ext.P20 study on medicine pricing issues as per which India requires to develop a National Cancer Policy for the prevention, diagnosis and treatment of cancer, with specific attention to the payment required for the care.

iv. As to whether the medicines 'Ribociclib' and 'Palbociclib' are interchangeable, she referred to the counter affidavit of the 1st respondent dated 01.11.2022, as per which both medicines are effective only as regards the IVth stage of cancer, whereas in the initial stage, Ribociclib requires to be administered.

v. She would add that even as per the counter affidavit filed by the 9th respondent and the averments in paragraphs 9 and 10, Palbociclib is a substitute only for the treatment of advanced stages.

vi. She pointed out that the statements/affidavits filed by respondents 11, 13 and 14 would point out that the medicine Palbociclib can be used for treatment of advanced or Metastatic stage of cancer.

vii. In view of the afore, it is her submission that the provisions of Section 100 of the Act ought to have been invoked by the Government. She would further elaborate that the patents issued to the manufacturing companies are subject to the general principles laid down under Section 83; when the patents are used, and when the medicines are not made available at affordable prices to the public, Section 100 would be attracted.

viii. She would therefore submit that the term "may" used under Section 100 requires to be taken as "shall," and the Government requires to intervene. According to her, the patients are not coming under the framework of the Act, and

therefore the Government is considered as the custodian/trustee of the interest of the patients, which is all the more a reason for the Central Government to interfere.

ix. She sought to rely on the judgments of the Apex Court, this Court as well as various judgments of the other High Courts in support of the afore submissions.

x. She pointed out that though the deceased had filed a representation before the Central Government, that came to be rejected pursuant to Ext.R1(b) dated 07.10.2022, the considerations therein being flawed.

xi. She would submit that though the writ petition was presented also seeking relief under Section 92, insofar as Section 92 provides for a company to come forward to seek license thereafter, and since there is an adjudicating process prescribed thereunder, only Section 100 of the Act is the viable option. Therefore, she submits that the applicability of Section 100 alone is pressed into service.

10. Sri.Rahul Bajaj, who is an intervenor in this matter (additional 7th respondent), apart from adopting the submissions made by Smt.Maitreyi sought to rely on **Devika Biswas v. Union of India and Others [(2016) 10 SCC 726]**, and **Mohd. Ahmed (Minor) v. Union of India and Others [(2014) SCC Online Del 1508]**, to contend that access to life-saving

medicines is within the ambit of the right to health under Article 21. He relied on **Navtej Singh Johar and Others v. Union of India [(2018) 10 SCC 1]** to contend that the State require to take steps to secure access to affordable patented medicines. He relied on the judgment of the Apex Court in **Gujarat Urja Vikas Nigam Limited v. Mr.Amit Gupta and Ors.[(2021) 7 SCC 209]** to contend that this Court requires to make appropriate suggestions for making the outcome of this litigation practically workable.

11. Sri.Gopakumar, the learned counsel for respondents 10 and 15, would submit that:

i. The 10th respondent is the husband of the deceased petitioner. On account of the high price of the medicine, the deceased was not able to afford the cost of the medicine Ribociclib.

ii. The 15th respondent, a Breast Cancer patient, is also a lawyer who is to spend around Rs.7.90 lakhs every year towards the medicine Ribociclib.

iii. The per capita income in India is Rs.2.19 lakhs, and this itself is a pointer to show that the medicine Ribociclib is not affordable for the majority of the population.

iv. Though respondents 8 and 9 are speaking much about the research and development expenditure, details thereof are not provided by them.

v. Patent under the Act is a conditional one.

vi. The State has a duty under Article 47 of the Constitution of India to improve public health.

12. Sri.Sreekumar, the learned ASGI, would contend that:

i. The question as to whether Section 92/100 of the Act requires to be invoked has been considered in *extenso* by the Central Government as evidenced by Ext.R1(b) order dated 07.10.2022.

ii. Though the writ petition has been instituted contending that the medicine is not affordable, no required data is provided.

iii. He would add that Section 92 is applicable only in the circumstances stated thereunder and not in any other circumstances.

iv. As regards Section 100, it is contended that the same is attracted when an invention requires to be "used" for the "purposes of Government" and not in a situation like the case herein.

13. Smt.O.M.Shalina, the learned Deputy Solicitor General of India (DSGI), appeared on behalf of the 4th respondent and

would contend that:

i. The prayer made in the writ petition is for the issuance of a writ of mandamus. However, it is not demonstrated that a request to invoke the provisions under Section 100 of the Act was made before the Government; hence, the mandamus cannot be issued.

ii. As regards the invocation of Section 92 of the Act, the Government has issued Ext.R1(b) after examining all the aspects, which has not been challenged by anyone.

iii. She further adds that this Court could not mould a relief and set aside Ext.R1(b) without there being any challenge to the same.

iv. She refers to the provisions of the Drugs (Price Control) Order, 2013, (for short, the 'Order') framed by the Government under the enabling provisions of the Essential Commodities Act, 1955, to state that the medicine Ribociclib is a non-scheduled drug and, under paragraph 20 of the order, the Government has been monitoring the price of the same and has also capped the price.

v. Even the provisions of paragraph 32 of the afore Order providing for non-application of the provisions of the Order would not apply to the medicine in question since the respective companies do not have a case that the same is developed through "indigenous Research and Development".

vi. The Government has already reduced the basic customs

duty for the medicine Ribociclib with effect from 01.02.2026, on account of which, the price for 21 tablets during January and March at Rs.24,355/- came down to Rs.22,217.85 during April and thereafter went again upward to Rs. 22,335/- during July.

vii. He sought to place considerable reliance on the judgment of the Karnataka High Court in W.P.No.11057 of 2019 dated 30.11.2022, to state that the writ court is not to interfere with the policy decision of the Government.

14. Sri.Krishna, the learned Senior Panel Counsel, would contend that:

i. Section 100 of the Act starts with a non-obstante clause; the same requires to be enforced "for the purposes of Government" in accordance with the provisions of Chapter XVII of the Act.

ii. Therefore, he would state that the meaning of the term "use of invention for the purposes of Government" is to be read along with Section 99 under Chapter XVII.

15. Sri.Kodianthara, the learned Senior Counsel, instructed by Sri.John Vithayathil, the learned counsel for the 9th respondent company, which manufactures the medicine "Ribociclib" on the basis of the patent, would contend that:

i. Section 100 can be invoked only when the patent requires to be used exclusively "for the purposes of Government". He refers to the provisions of Section 99 of Chapter XVII, and states that, the meaning of the term "use of invention for the purposes of Government" having been separately laid down under Section 99, the prayer made in the writ petition is not to be granted. In other words, he states that Section 100 is applicable only to cases where the Central Government requires the use of the patent "for the purposes of Government", and not in an instance where the Government is informed that there is a requirement for reduction of the price.

ii. He sought to rely on the principles laid down by a learned Single Judge of the Nagpur Bench of the Bombay High Court in **Garware Wall Ropes Ltd., Pune v. M/s A.I.Chopra, Engineers and Contractors, Nagpur and another [(2008) SCC OnLine BOM 1225]** in this regard.

iii. With reference to the averments in paragraph 15 of the counter affidavit filed by the 9th respondent, it is pointed out that, among various countries, the said respondent is charging the lowest price in India.

iv. He makes reference to a notification issued by the National Pharmaceutical Pricing Authority pursuant to which a 30% cap on the trade margin on Ribociclib has been imposed, on account of which, it is clear that the Government has already intervened so as to regulate the price of the medicine.

v. Without prejudice, he referred to the opinion of respondents 11, 13 and 14 that the medicine Palbociclib is a substitute for Ribociclib, and contended that the prayers in the writ petition are purely academic.

16. Sri.Hemant Singh, who also made submissions on behalf of the 9th respondent, would contend that:

i. The 9th respondent has invented the medicine Ribociclib through a long process involving failed trials/inventions, innovations, investing huge amounts in human resources, research and development, and the research and development as above is only being encouraged by extending the full protection by granting patent.

ii. The protection through a patent, is actually a *quid pro quo* pursuant to which the patentee discloses the innovation to the public and, on the expiry of the patent, the technology can be used by the public.

iii. In view of the afore, it is his submission that pricing is not to be a criterion for denying/restricting a patent.

iv. Section 100 requires to be read along with the provisions of Section 156 also, and therefore, the patent binds the Government just like any other individual.

v. With reference to the statistics provided in paragraph 14 of the counter affidavit filed by the 9th respondent, he states that CDK 4/6 inhibitors like Ribociclib are being

used only by 13% of total Breast Cancer patients and the rest of the patients go for various other treatment options like chemotherapy, chemo plus Endocrine therapy, Endocrine therapy, etc. Therefore, he would add that the price of Ribociclib by itself cannot be a reason for invocation of the provisions of Section 100 of the Act.

vi. He would further state that what requires to be done is the detection of Breast Cancer at the early stage itself so that the same does not become a life-threatening one, when in India nearly 60% cases are diagnosed at a later stage of the disease, which makes the treatment difficult.

17. Sri.G.Shrikumar, the learned Senior Counsel instructed by Sri.Arun Kumar, the learned counsel for the 8th respondent, would contend that:

i. Originally in India it was only the "process" that was being patented, and at present it is the "product" that is being patented, and hence, the patent of the 8th respondent requires to be protected.

ii. He would state that the 8th respondent is manufacturing the medicine "Abemaciclib" which is also mentioned in various statements/reports/opinions of respondents 11, 13 and 14 as CDK 4/6 inhibitor for treatment of Metastatic Breast Cancer. He contends that since there was no prayer as regards the afore medicine *qua* the provisions of the Act,

the 8th respondent's patent is not to be disturbed.

iii. He relied on the Single Bench judgment of this Court in **Aravindan K.P. (Dr.) v. Union of India [2022 KHC Online 7761]**, the judgment of the Division Bench of this Court in W.P(C) No.29182 of 2009, the judgment of the Apex Court in **Distribution of Essential Supplies and Services During Pandemic, In Re [(2021) 18 SCC 201]**, etc., in support of the afore.

18. Sri.Praveen Anand, the learned counsel for the 8th respondent, also made submissions as under:

i. The amounts spent on the inventions/research cannot be overlooked, and such investment is also being protected under the Act.

ii. The 8th respondent applied for a patent in 2008 and has been granted the same only in 2018, on account of which, it has protection only for another 10 years from 2018, which in effect is only 50% of the total protection.

iii. He relied on the averments contained in paragraph 52 of the counter affidavit to point out that the company is offering free-of-charge medicines after the initial 9 months of therapy and for early Breast Cancer patients one pack of Ramiven® is offered free of charge for the entire duration of therapy upon purchase of three packs.

19. Sri.T.A.Shaji, the learned Senior Counsel instructed by

Sri.Atul Shaji, the learned Standing Counsel for the 13th respondent (RCC), also made submissions. He would invite the attention of this Court to a report dated 20.08.2026 from the RCC, as per which the three medicines "Palbociclib, Ribociclib and Abemaciclib" are the three available medicines for treatment of stage IV Breast Cancer.

20. I have considered the rival contentions as well as the connected records.

21. Before proceeding to consider the submissions made on the applicability of Section 100 of the Act, the question as to whether the medicine "Palbociclib" can be used as a substitute for "Ribociclib" requires to be considered. The learned *Amicus Curiae* has emphatically pointed out that "Palbociclib" can only be used in the advanced stages, whereas "Ribociclib" is being administered at the early stages.

22. In this regard, the counter affidavit filed by the additional 14th respondent dated 14.08.2026 requires to be noticed. In the said affidavit, with reference to the details

available with that office, it is pointed out that Palbociclib is used in the treatment of "advanced or Metastatic Breast Cancer". However, as regards Ribociclib, it is pointed out that the same is being used for "early Breast Cancer". The additional 13th respondent (RCC) in its report dated 20.08.2026 has also pointed out that "Palbociclib" is being administered for "stage IV" Breast Cancer. The expert opinion as above shows that "Palbociclib" and "Ribociclib" are not interchangeable.

23. In the light of the afore, this Court proceeds to consider the submissions made with respect to the applicability of Section 100 of the Act.

24. The main issue arising for consideration is as to whether the Central Government requires to intervene with reference to the provisions of Section 100 of the Act. As already noticed, the learned *Amicus Curiae* contends that the Government has to intervene and use the invention for its purposes, and such a direction requires to be issued by this Court. Section 100 of the Act reads as under:

"**100. Power of Central Government to use inventions for purposes of Government**.—(1) Notwithstanding anything contained in this Act, at any time after an application for a patent has been filed at the patent office or a patent has been granted, the Central Government and any person authorised in writing by it, may use the invention for the purposes of Government in accordance with the provisions of this Chapter.

(2) Where an invention has, before the priority date of the relevant claim of the complete specification, been duly recorded in a document, or tested or tried, by or on behalf of the Government or a Government undertaking, otherwise than in consequence of the communication of the invention directly or indirectly by the patentee or by a person from whom he derives title, any use of the invention by the Central Government or any person authorised in writing by it for the purposes of Government may be made free of any royalty or other remuneration to the patentee.

(3) If and so far as the invention has not been so recorded or tried or tested as aforesaid, any use of the invention made by the Central Government or any person authorised by it under sub-section (1), at any time after grant of the patent or in consequence of any such communication as aforesaid, shall be made upon terms as may be agreed

upon either before or after the use, between the Central Government or any person authorised under sub-section (1) and the patentee, or, as may in default of agreement be determined by the High Court on a reference under section 103:

Provided that in case of any such use of any patent, the patentee shall be paid not more than adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent.

(4) The authorisation by the Central Government in respect of an invention may be given under this section, either before or after the patent is granted and either before or after the acts in respect of which such authorisation is given or done, and may be given to any person, whether or not he is authorised directly or indirectly by the applicant or the patentee to make, use, exercise or vend the invention or import the machine, apparatus or other article or medicine or drug covered by such patent.

(5) Where an invention has been used by or with the authority of the Central Government for the purposes of Government under this section, then, except in case of national emergency or other circumstances of extreme urgency or for non-commercial use, the Government shall notify the patentee as soon as practicable of the fact and

furnish him with such information as to the extent of the use of the invention as he may, from time to time, reasonably require; and where the invention has been used for the purposes of a Government undertaking, the Central Government may call for such information as may be necessary for this purpose from such undertaking.

(6) The right to make, use, exercise and vend an invention for the purposes of Government under sub-section (1) shall include the right to sell, on non-commercial basis, the goods which have been made in exercise of that right, and a purchaser of goods so sold, and a person claiming through him, shall have the power to deal with the goods as if the Central Government or the person authorised under sub-section (1) were the patentee of the invention.

(7) Where in respect of a patent which has been the subject of an authorisation under this section, there is an exclusive licensee as is referred to in sub-section (3) of section 101, or where such patent has been assigned to the patentee in consideration of royalties or other benefits determined by reference to the use of the invention (including payments by way of minimum royalty), the notice directed to be given under sub-section (5) shall also be given to such exclusive licensee or assignor, as the case may be, and the reference to the patentee in sub-section (3) shall be deemed to

include a reference to such assignor or exclusive licensee."

True, Section 100 of the Act begins with a non-obstante clause. However, it requires to be noticed further that the Central Government or any person authorised in writing by it is permitted to "use the invention for the purposes of Government" in accordance with the provisions of Chapter XVII. Therefore, even on the face of the non-obstante clause, the provisions of Section 99 of the Act providing for a meaning for the term "use of invention for the purposes of Government" requires to be noticed, which reads as follows:

> "**99. Meaning of use of invention for purposes of Government**.—(1) For the purposes of this Chapter, an invention is said to be used for the purposes of Government if it is made, used, exercised or vended for the purposes of the Central Government, a State Government or a Government undertaking.
>
> (2) ******
>
> (3) Nothing contained in this Chapter shall apply in respect of any such importation, making or using of any machine, apparatus or other article or of any such using of any process or of any such importation, using or

> distribution of any medicine or drug, as may be made by virtue of one or more of the conditions specified in section 47."

It is also to be further seen that Chapter XVII, under which Sections 99 and 100 are provided, provides for "use of invention for the purposes of Government" and the acquisition of invention by the Central Government.

25. Therefore, under Section 99 of the Act, an invention is said to be used for the purposes of Government if the same is made, used, exercised or vended for the purposes of Central Government, State Government or a Government undertaking. In other words, the patent/invention requires to be used by the Government alone under the provisions of Section 100 read with the provisions of Section 99. Here, the prayer made is for a direction to the Government to invoke Section 100 so that the invention by the patent holder is used for safeguarding the interest of the public at large.

26. The learned ASGI, the learned DSGI, and the learned Senior Counsel for respondents 8 and 9, as already noticed,

contended that the provisions of Section 100 of the Act would not apply since the same could be invoked only for the purposes of Government and for no other reasons. In other words, according to them, invoking Section 100, the Government cannot manufacture the medicine using the inventions which have been patented by respondents 8 and 9 and thereafter supply the same to the needy patients free of cost or at subsidised price. At first blush, the said submission appears attractive, especially in light of the provisions under Section 99, which defines the term "use of invention for the purposes of Government" as stipulated thereunder.

27. However, the matter requires to be considered with reference to the various subsections under Section 100 also. For instance, sub-section (4) entitles the Government to authorise any person to

i. Make
ii. Use
iii. Exercise, or
iv. Vend

the invention or import of the machine, apparatus or other article or "medicine or drug" covered by such patent. Similarly, sub-section (6) also makes it clear that the right to make, use, exercise and vend an invention shall include the right to sell, on non-commercial basis, the goods which have been made in exercise of that right. In view of the afore provisions, this Court is of the opinion that the term "for the purposes of Government" requires to be interpreted also taking into account the right to vend/sell the goods made using the patent and invention on a non-commercial basis to a purchaser. The provisions of Section 100 impose no restriction on who the purchaser could be. When that be so, the provisions under Section 100 would include the entitlement of the Government to use the patent or invention for manufacturing the medicine covered by the patent and sell the same on a non-commercial basis to a person who can be none other than the needy patient. This position is made further clear by the specific inclusion of "medicines or drugs" under sub-section (4).

28. Considerable reliance was placed on the judgment of the Nagpur Bench of the Bombay High Court in **Garware Wall Ropes Ltd**. (*supra*) by the respondents (the Government and the Companies) to state that the term "purposes of Government" is having a restrictive meaning. The operative portion of the afore judgment needs to be noticed as under:

> "21. Perusal of the above provisions show that the said terminology 'merely of its own use' has been deliberately used in Section 47 of the Act in contrast to the provisions of Sections 99 and 100 of the Patents Act, viz. for the purposes of Government, for the purposes of Central Government, State Government or Government undertaking. The words 'merely of its own use' have been utilized with a definite purpose and it cannot be said that the Parliament used different words in Sections 47, 99 and 100 of the Act for no reasons or for no intentions. In my opinion, all these words 'merely of its own use' would mean use for the purposes of the Government by any department of the Government and use by servants and agents of the Government in performance of their duties/in discharge of their duties assigned to them irrespective of who is benefited by such use. This would not include use by any other person like contractor of railways and the meaning is

strictly restricted to the direct use by any department of the Government or its servants in the performance/in the discharge of their duties. This is all the more so, because for such use contemplated by Section 47 of the Act, no payment of royalty is at all contemplated to the patentee. In terms of the doctrine of 'eminent domain' Parliament/Government is entitled to make a patent subject to such conditions as are to be found in Section 47 of the Act. In a similar manner a look at Sections 35 to 42 contained in Chapter VII of the Act will reveal that for the security and defence of India all rights of the patentees have been curtailed as the same is a sovereign function. No patentee can claim a right on a high pedestal than the Government performing sovereign function.

22. It is, thus, clear from the above provisions of Sections 99 and 100 of the Act that by using the words 'for the purposes of Government' as against 'merely of its own use' in Section 47 of the Act, the use of inventions stands extended even to the Central Government, State Government or a Government Undertaking. According to me, these provisions have been made in order that the patents can be utilized by Central Government, State Government for the purposes other than purely departmental in the discharge of duties or the sovereign functions but in accordance with the terms and conditions laid down in this Chapter XVII. Under these provisions

> even a third person i.e. contractor like respondent No.1 can be allowed to use the patent for the purposes of Government or Government undertakings. But then that is upon the agreement or licence given by the patentee to such third person and upon, of-course, the payment of royalty etc. It is clear to me that the Central Government or State Government are not entitled to use a patent free of cost as already held by me for any other purposes than 'merely of its own use' i.e. for performing the Governmental functions by the Government servants or Government departments in performance of their duties or in the discharge of their duties. The mechanism, therefore, provided by Chapter XVII is to allow even the third party, Central Government and State Government (for use other than 'merely of its own use').”
>
> (Underlining supplied)

True, the Bombay High Court held that the term “purposes of Government” can only be of meaning: purposes of Government by any department of the Government and use by servants and agents of the Government in performance/discharge of their duties. However, it is necessary to notice the distinction, as observed by the Bombay High Court, between the provisions of Section 100 and Section 47 of the Act, which uses the words

"merely of its own use". The term "purposes of Government" also includes the vending of articles made using the invention, as laid down under sub-sections (4) and (6) of Section 100, as discussed earlier, and the same cannot be disputed in view of the clear language.

29. Article 47 of the Constitution of India has laid down that the State has a duty to improve public health, being a primary duty of the State.

30. Therefore, the term "purposes of Government" also includes the duty of the Government/State to improve public health as mandated under Article 47 of the Constitution of India. This has to include the use of the patent, manufacturing of the medicines, and supplying the same on a non-commercial basis under Section 100(6) of the Act to the needy patients. The Nagpur Bench of the Bombay High Court has also, in paragraph 22 of the afore judgment, held that the provisions under Section 100 as well as Section 47 have been made so that the patents can be utilised by the Central/State Government for purposes

other than purely departmental in the discharge of duties or the sovereign functions.

31. The reliance placed by the Government as well as respondents 8 and 9 on the judgment of the Apex Court in **Distribution of Essential Supplies and Services During Pandemic, *In Re*** (*supra*) may also not be apposite, since the Apex Court also, in paragraphs 46 and 47 of the afore judgment, with reference to Section 100 of the Act, found as under:

> "46. …….. Further, under Section 100 of the Patents Act, the Central Government can authorise certain companies to use any patents for the "purpose of the Government". Indian companies can begin manufacturing the drugs while negotiating the royalties with the patentees. If the Central Government or its authorised company is not able to reach an agreement with the patentee, the High Court has to fix the reasonable royalty that is to be paid to the patentee. ……
>
> 47. The utilisation of these flexibilities has also been detailed in the Trade Related Aspects of Intellectual Property Rights Agreement ("TRIPS"). Even as TRIPS obliges countries to ensure a minimum level of patent protection, it creates a permissive regime for the carving

> out of exceptions and limitations that further public health objectives. This is evident from a conjoint reading of Articles 7, 8, 30 and 31 of TRIPS. Article 7 outlines the objectives of the TRIPS as being to ensure the effective enforcement of intellectual property in a way that, inter alia, is "conducive to social and economic welfare". Article 8 gives member countries the freedom to take measures that protect public health and nutrition. Article 8(2) allows for the taking of TRIPS-compatible measures aimed at preventing the abuse of intellectual property rights. Articles 30 and 31 deal with exceptions to the rights of patent owners, by allowing grant of compulsory licences. It leaves countries with significant breathing space to determine how the compulsory licensing or government-use levers can be triggered. While such determinations must be made on the individual merits of each case, the aforesaid caveat does not apply when the compulsory licence grant is for national emergency, extreme urgency or public non-commercial use."
>
> (Underlining supplied)

Therefore, the Apex Court has also held that Section 100 is required to be enforced in the interest of the public at large, particularly to ensure the protection of patients. Reference also needs to be made to the provisions of Articles 7/8 of TRIPS,

wherein it is made clear that the very aim of providing intellectual property rights is for the "mutual advantage of producers and users" alike and also to empower the member nations to "adopt measures necessary to protect public health and nutrition".

32. The matter also requires to be approached with reference to the mandate under Article 21 of the Constitution of India. The right to self-preservation of one's life is to be accorded paramount importance by virtue of the mandate under Article 21. In **Pt. Parmanand Katara v. Union of India and Others [(1989) 4 SCC 286]**, the Apex Court has categorically reiterated about the duty of the Government for preservation of life in the following lines:

> "7. There can be no second opinion that preservation of human life is of paramount importance. That is so on account of the fact that once life is lost, the status quo ante cannot be restored as resurrection is beyond the capacity of man. The patient whether he be an innocent person or be a criminal liable to punishment under the laws of the society, it is the obligation of those who are in charge of the health of the community to preserve life so that the innocent may be protected and the guilty may be punished.

> Social laws do not contemplate death by negligence to tantamount to legal punishment.
>
> 8. Article 21 of the Constitution casts the obligation on the State to preserve life. The provision as explained by this Court in scores of decisions has emphasised and reiterated with gradually increasing emphasis that position. A doctor at the government hospital positioned to meet this State obligation is, therefore, duty bound to extend medical assistance for preserving life. Every doctor whether at a government hospital or otherwise has the professional obligation to extend his services with due expertise for protecting life. No law or State action can intervene to avoid/delay the discharge of the paramount obligation cast upon members of the medical profession. The obligation being total, absolute and paramount, laws of procedure whether in statutes or otherwise which would interfere with the discharge of this obligation cannot be sustained and must, therefore, give way."

33. Again, the Apex Court in **Paschim Banga Khet Mazdoor Samity and Others v. State of W.B. and Another [(1996) 4 SCC 37]** spoke about the Government's duty to consider the preservation of life as having paramount importance in the following lines:

"9. The Constitution envisages the establishment of a welfare State at the federal level as well as at the State level. In a welfare State the primary duty of the Government is to secure the welfare of the people. Providing adequate medical facilities for the people is an essential part of the obligations undertaken by the Government in a welfare State. The Government discharges this obligation by running hospitals and health centres which provide medical care to the person seeking to avail of those facilities. Article 21 imposes an obligation on the State to safeguard the right to life of every person. Preservation of human life is thus of paramount importance. ……

……..

16. It is no doubt true that financial resources are needed for providing these facilities. But at the same time it cannot be ignored that it is the constitutional obligation of the State to provide adequate medical services to the people. Whatever is necessary for this purpose has to be done. In the context of the constitutional obligation to provide free legal aid to a poor accused this Court has held that the State cannot avoid its constitutional obligation in that regard on account of financial constraints. [See: *Khatri (II) v. State of Bihar*, SCC at p. 631.] The said observations would apply with equal, if not greater, force in the matter of

discharge of constitutional obligation of the State to provide medical aid to preserve human life. In the matter of allocation of funds for medical services the said constitutional obligation of the State has to be kept in view. It is necessary that a time-bound plan for providing these services should be chalked out keeping in view the recommendations of the Committee as well as the requirements for ensuring availability of proper medical services in this regard as indicated by us and steps should be taken to implement the same. The State of West Bengal alone is a party to these proceedings. Other States, though not parties, should also take necessary steps in the light of the recommendations made by the Committee, the directions contained in the memorandum of the Government of West Bengal dated 22-8-1995 and the further directions given herein.

17. The Union of India is a party to these proceedings. Since it is the joint obligation of the Centre as well as the States to provide medical services, it is expected that the Union of India would render the necessary assistance in the improvement of the medical services in the country on these lines."

34. The Apex Court in **Vincent Panikurlangara v. Union of India and Others [(1987) 2 SCC 165]** has considered an

issue regarding withdrawal of licenses of manufacturers of drugs which are injurious and harmful to the life of patients and held as under:

> "16. A healthy body is the very foundation for all human activities. That is why the adage "*Sariramadyam Khaludharma Sadhanam*". In a welfare State, therefore, it is the obligation of the State to ensure the creation and the sustaining of conditions congenial to good health. This Court in *Bandhua Mukti Morcha v. Union of India* aptly observed: (SCC p. 183, para 10)
>
> > It is the fundamental right of everyone in this country, assured under the interpretation given to Article 21 by this Court in *Francis Mullin case* to live with human dignity, free from exploitation. This right to live with human dignity enshrined in Article 21 derives its life breath from the Directive Principles of State Policy and particularly clauses (e) and (f) of Article 39 and Articles 41 and 42 and at the least, therefore, it must include protection of the health and strength of the workers, men and women, and of the tender age of children against abuse, opportunities and facilities for children to develop in a healthy manner and in conditions of freedom and dignity, educational facilities, just

> and humane conditions of work and maternity relief. These are the minimum requirements which must exist in order to enable a person to live with human dignity and no State — neither the Central Government nor any State Government — has the right to take any action which will deprive a person of the enjoyment of these basic essentials.

While endorsing what has been said above, we would refer to Article 47 in Part IV of the Constitution. That article provides:

> The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health.

This article has laid stress on improvement of public health and prohibition of drugs injurious to health as one of the primary duties of the State. In *Akhil Bharatiya Soshit Karamchari Sangh v. Union of India* this Court has pointed out that: (SCC pp. 308-09, para 123)

> The fundamental rights are intended to foster the ideal of a political democracy and to

> prevent the establishment of authoritarian rule but they are of no value unless they can be enforced by resort to courts. So they are made justiciable. But, it is also evident that notwithstanding their great importance, the Directive Principles cannot in the very nature of things be enforced in a court of law.... It does not mean that directive principles are less important than fundamental rights or that they are not binding on the various organs of the State.

In a series of pronouncements during the recent years this Court has culled out from the provisions of Part IV of the Constitution these several obligations of the State and called upon it to effectuate them in order that the resultant pictured by the Constitution Fathers may become a reality. As pointed out by us, maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of the community and on the betterment of these depends the building of the society of which the Constitution makers envisaged. Attending to public health, in our opinion, therefore, is of high priority — perhaps the one at the top.

17. None of the parties before us claimed, and perhaps rightly, that the prevailing state of affairs in this regard

> is a commendable one. The technical aspects which arise for consideration in a matter of this type cannot be effectively handled by a court. Similarly the question of policy which is involved in the matter is also one for the Union Government — keeping the best of interests of citizens in view to decide. No final say in regard to such aspects come under the purview of the court. Yet there are certain contentions raised by the petitioner which deserve serious consideration and we would now proceed to deal with them."
>
> (Underlining supplied)

Therefore, there can be no doubt that the Government is required to provide all necessary facilities to citizens to ensure access to healthcare, including access to life-saving treatment, as in the case at hand. As pointed out in the case at hand, the high cost of the drug in question virtually defeats the requirements under Articles 21 and 47 of the Constitution of India. This is because, as already noticed, the "purposes of Government" would encompass the mandate contained in Articles 21 and 47 referred to above.

35. Again, a reference also requires to be made to the

provisions under Section 83 of the Act, the relevant portions of which read as under:

> "**83. General principles applicable to working of patented inventions**.—Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely:—
>
> .....
>
> (d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;
>
> (e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;
>
> .....
>
> (g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public."
>
> (Underlining supplied)

Therefore, the fact that the patent granted is subject to the right of the Government to promote public health and the public interest has been made very clear by the incorporation of the

above caveat. Further sub-section (g) also speaks about the requirement/duty to provide patented inventions at reasonably affordable prices to the public.

36. At this juncture, the submissions made by Smt.Maitreyi with reference to the Lok Sabha debates in connection with the Patent (Amendment) Bill, 2002 also require to be noticed. In response to certain apprehensions by the Parliamentarians, it has been clarified that under the provisions of Section 100 of the Act, the Government can use the patent at any time "in the interest of the public health system". It is further clarified that the Government can "procure it and sell it to the hospitals or they can give it to third parties". Therefore, the intention behind the provisions of Section 100 is also made clear as noticed above.

37. In the light of the afore, this Court is of the opinion that the provisions of Section 100 of the Act are required to be invoked in circumstances where the Government is required to intervene, such as when the medicine is unaffordable on account of its exorbitant price.

38. Even on the face of the afore, the question arises as to whether this Court is to issue a positive direction to the Government to exercise the power under Section 100 of the Act as interpreted above. This is particularly so since there can be no dispute that the patent has been granted in recognition of the new invention relating to the medicine in question. Such a grant of a patent extends utmost protection to the patent holder so that he can utilize the same commercially. On account of the protection as above, the patent holder enjoys an exclusion of any other person from using the invention, till such time validity of the patent continues. Even the Government is bound by the patent, as has been clearly stated in Section 156 of the Act. If such sanctity is not being extended to a patentee, that would be a factor which would be counterproductive insofar as no one will come forward to register their patent under the statute. If this happens, the inventions would not be used by anyone, which is detrimental to the interest of the society at large. It is in the light of the afore that Parliament sought to enact the statute,

regulating and consolidating the law relating to patents in the year 1970, more particularly on the basis of the recommendations of the Justice N.Rajagopala Ayyangar Committee. The statute so consolidated aims at protecting the process leading to the manufacture of the article by patenting the same.

39. In the light of the afore, it is for the Central Government to consider whether Section 100 of the Act requires to be invoked since ultimately the same is a policy decision.

40. True, the Apex Court in **Distribution of Essential Supplies and Services During Pandemic, *In Re*** (*supra*), has found that Section 100 of the Act requires to be invoked in appropriate circumstances as discussed therein. At the same time, after finding so, the Apex Court has further found as under:

> "49. Whether and if so, the extent to which these provisions should be utilised is a policy decision for the Central Government. We have flagged the issue for its consideration. We have only outlined the legal framework within which the Central Government can possibly consider compulsory licensing and government acquisition of patents. The Central Government is free to choose any

other course of action that it deems fit to tackle the issue of vaccine requirements in an equitable and expedient manner, which may involve negotiations with domestic and foreign producers of vaccines. We clarify that it is up to the Central Government to choose the best possible measures it can undertake during the current crisis keeping in mind that public interest is of paramount importance."

(Underlining supplied)

Thus, it is for the Central Government to consider whether Section 100 requires to be invoked after collecting the necessary statistics.

41. The Apex Court, again in **State of Punjab v. Ram Lubhaya Bagga [(1998) 4 SCC 117]**, has found as under:

"25. Now we revert to the last submission, whether the new State policy is justified in not reimbursing an employee, his full medical expenses incurred on such treatment, if incurred in any hospital in India not being a government hospital in Punjab. Question is whether the new policy which is restricted by the financial constraints of the State to the rates in AIIMS would be in violation of Article 21 of the Constitution of India. So far as questioning the validity of governmental policy is concerned in our view it is not normally within the domain of any court, to weigh the pros

and cons of the policy or to scrutinize it and test the degree of its beneficial or equitable disposition for the purpose of varying, modifying or annulling it, based on howsoever sound and good reasoning, except where it is arbitrary or violative of any constitutional, statutory or any other provision of law. When Government forms its policy, it is based on a number of circumstances on facts, law including constraints based on its resources. It is also based on expert opinion. It would be dangerous if court is asked to test the utility, beneficial effect of the policy or its appraisal based on facts set out on affidavits. The court would dissuade itself from entering into this realm which belongs to the executive. It is within this matrix that it is to be seen whether the new policy violates Article 21 when it restricts reimbursement on account of its financial constraints.

26. When we speak about a right, it correlates to a duty upon another, individual, employer, government or authority. In other words, the right of one is an obligation of another. Hence the right of a citizen to live under Article 21 casts obligation on the State. This obligation is further reinforced under Article 47, it is for the State to secure health to its citizen as its primary duty. No doubt the Government is rendering this obligation by opening government hospitals and health centres, but in order to make it meaningful, it has to be within the reach of its

people, as far as possible, to reduce the queue of waiting lists, and it has to provide all facilities for which an employee looks for at another hospital. Its upkeep, maintenance and cleanliness has to be beyond aspersion. To employ the best of talents and tone up its administration to give effective contribution. Also bring in awareness in welfare of hospital staff for their dedicated service, give them periodical, medico-ethical and service-oriented training, not only at the entry point but also during the whole tenure of their service. Since it is one of the most sacrosanct and valuable rights of a citizen and equally sacrosanct sacred obligation of the State, every citizen of this welfare State looks towards the State for it to perform its this obligation with top priority including by way of allocation of sufficient funds. This in turn will not only secure the right of its citizen to the best of their satisfaction but in turn will benefit the State in achieving its social, political and economical goal. For every return there has to be investment. Investment needs resources and finances. So even to protect this sacrosanct right finances are an inherent requirement. Harnessing such resources needs top priority."

To the same effect are the principles laid down in **Brij Mohan Lal v. Union of India [(2012) 6 SCC 502]** (Paragraphs 96 and 99).

42. This is especially so, since this Court is of the opinion that the required data to decide whether the particular medicines in question are affordable or not, has not been brought on record. The data requires to be collected by the Government, as to the actual number of persons affected with the particular type of cancer, the number of patients consuming the medicines in question, the cases where such medicines are not consumed by patients on account of the alleged exorbitant price, etc., by collecting such details from the hospitals across the country. It also requires to be noticed that, as contended by some of the respondents, the Government itself is stated to have introduced various schemes for supplying medicines at subsidised prices, etc. But the number of patients who have been benefited from such schemes requires to be evaluated. The Government is also required to consider the effectiveness of such schemes and whether they require to be extended any further, especially since it is pointed out by the Government and the companies that the

cancer medicines are brought under price control with reference to the capping of the price as noticed above. Further, the findings in the judgment as regards the scope of Section 100 of the Act would have applicability as against several other life saving drugs also. However, only the manufacturers of two such medicines are before this Court, and submissions were made on that basis alone. Therefore, it is for the Government to ponder as regards the requirement to invoke Section 100 in appropriate cases after collecting the required data.

43. More recently, the Apex Court in **Siddharth Dalmia v. Union of India [2025 (3) KHC 349 (SC)]** has considered the question as to whether the affairs of the private hospital with reference to pricing of drugs, equipment, etc. could be regulated, as under:-

> "14. In this backdrop, would it be prudent for the Union of India or the States to introduce a policy which regulates each and every activity within the compound of these private hospitals? Will such a policy discourage persons to come forward and invest in the health industry throughout the country? Most importantly, why

should the States not adopt such economic policies whereunder they ensure dedicated apportionments towards the development of basic infrastructure, including institutions for health services; and till such time the States are able to do so, whether stringent measures which would stall private entities from coming forward, should be allowed to be introduced?

15. All these issues are undoubtedly of paramount public importance. It, however, seems to us that such issues primarily involve policy decisions, for which the policy-makers are the best equipped to take a holistic view and formulate the guidelines as may be required (In Re: S.6A of the Citizenship Act 1955, 2024 SCC OnLine SC 2880; Suman Kumar v. Union of India, [2023 SCC OnLine SC 1750; Transport & Dock Workers Union v. Mumbai Port Trust, [2011 (2) SCC 575]; Govt. of A.P. v. N. Subbarayudu, [2008 (14) SCC 702], to safeguard the patients or their attendants from exploitation while simultaneously, ensuring that there is no discouragement and unreasonable restriction on private entities from entering the health sector.

16. It may be noticed that the subject of public health and sanitation, hospitals, and dispensaries falls under List-II - the State List - and, therefore, any such

measure, as illustrated above, must be taken by the State Governments, keeping their local conditions in mind.

17. To sum up, it may not be advisable for this Court to issue mandatory directions which may hamper the growth of hospitals in the private sector; but parallelly, it is necessary to sensitize the State Governments re: the problem of unreasonable charges and exploitation of patients in private hospitals."

(Underlining supplied)

Therefore, ultimately it is for the Central Government to consider the question as to whether Section 100 of the Act requires to be invoked with reference to the factual position.

44. The 139th Report by the Department-Related Parliamentary Standing Committee on Health and Family Welfare on Cancer Care Plan and Management: Prevention, Diagnosis, Research and Affordability of Cancer Treatment published during September, 2022 also requires to be noticed. In the report of the Committee, after deliberation on the matter, has observed as under:-

"4.9.4 The Committee has been apprised that one among

> the five cancer insurance claims is by patient belonging to 36 to 45 years of age, thereby resulting into the loss or disruption of household income. As per the National Sample Survey Healthcare even average out of pocket spending on cancer care is too high. The out of pocket spending for cancer care in private facilities is about three times that of public facilities. About 40% of cancer hospitalization cases are financed mainly through borrowings, sale of assets and contributions from friends and relatives. Considering such a glaring gap in affordability when it comes to quality cancer care, the Committee feels that there is a strong need to make cancer care affordable through suitable interventions from both Government and private sectors."

It is for the Government to take note of the above and move forward accordingly.

In the result, I dispose of this writ petition with the following findings:

i. Provisions under Section 100 of the Act would also include the entitlement of the Government to use the patent or invention for manufacturing the medicine covered by the patent and sell the same to a person, including a needy patient, on a non-commercial basis.

ii. Section 100 of the Act is required to be invoked in circumstances where the Government is required to intervene, such as an instance where a medicine manufactured on the basis of a patent is being sold at an exorbitant price.

iii. The Government requires to collate the required data and arrive at a decision as to whether a particular medicine is affordable or not and, on that basis, proceed in accordance with Section 100 of the Act, if found necessary.

Before parting, I must also place on record the appreciation for the efforts, erudition, good grounding in legal principles and industry of Smt.Maitreyi Sachidananda Hegde, the learned *Amicus Curiae*, which was of much assistance to this Court.

EPILOGUE

Jnanpith Laureate and Padma Vibhushan awardee, late M.T.Vasudevan Nair, who was also a renowned screenplay writer in his highly acclaimed work "Sukrutham", has depicted, with great force, the plight of not just the patients of this despicable disease but also of their bystanders. In the film directed by

Sri.Harikumar, the protagonist, portrayed by the legendary Padma Bhushan awardee Sri.Mammootty, can be seen informing his doctor that he won't be opting for the injunction. He follows this with a heartbreaking monologue on how cancer patients and their bystanders end up pledging their entire lives to afford proper medical care, only to be left buried in mountains of debt. It is highly distressing that despite the passage of more than three decades since this story was adapted into the movie vocabulary, and won accolades at the National and State levels, and despite the growth of technology, the plight of patients and their families remains the same. The aim of art was, is, and always will be to bring the various realms of society closer and to make them more aware of the lives led by others. Yet, despite such heavy social cavalry, society and the situation have been stuck at a standstill in such cases. The Government, the people, and stakeholders should, as a joint venture, ensure that no man is refused or refuses treatment exclusively due to financial constraints. It is imperative that, we, as a community and as a system that caters

to billions, strike the balance between affordable access to medical treatment and maintaining adequate incentives.

Sd/-
HARISANKAR V.MENON
JUDGE

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APPENDIX OF WP(C) NO.18999 OF 2022

PETITIONER'S EXHIBITS:

EXHIBIT P1	**SEALED COVER**
EXHIBIT P2	**SEALED COVER**
EXHIBIT P3	**TRUE COPY OF THE NEWS ITEM DATED 08.03.2021 WITH THE TITLE 'NEW GLOBAL BREAST CANCER INITIATIVE HIGHLIGHTS RENEWED COMMITMENT TO IMPROVE SURVIVAL' APPEARED IN THE OFFICIAL WEBSITE OF THE WHO.**
EXHIBIT P4	**TRUE COPY OF THE PAPER WITH THE TITLE OVERVIEW OF BREAST CANCER AND IMPLICATIONS OF OVERTREATMENT OF EARLY-STAGE BREAST CANCER: AN INDIAN PERSPECTIVE', DATED 08.06.2020 PUBLISHED IN JCO GLOBAL ONCOL 6:789-798. © 2020 BY AMERICAN SOCIETY OF CLINICAL ONCOLOGY.**
EXHIBIT P5	**TRUE COPY OF THE ARTICLE BY DR. SADHANA KALA DATED 26.10.2020 PUBLISHED IN TIMES OF INDIA.**
EXHIBIT P6	**TRUE COPY OF THE PRESS RELEASE DATED 18.08.2020 ISSUED BY INDIAN COUNCIL OF MEDICAL RESEARCH ALONG WITH NATIONAL CANCER REGISTRY PROGRAMME.**
EXHIBIT P7	**TRUE COPY OF THE LETTER DATED 03.06.2021, AUTHORED BY AMOL PATEL, TVSGK TILAK, VINEET G GUPTA, ATUL BATRA, PRASHANT MEHTA, PURVISH PARIKH AND HEMANT MALHOTRA 'DYNAMICS OF SEQUENCING OF CYCLIN-DEPENDENT KINASE INHIBITORS AND COST EXPENDITURE ANALYSIS IN THE MANAGEMENT OF METASTATIC HORMONE-RECEPTOR POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR 2-NEGATIVE ADVANCED BREAST CANCER' PUBLISHED IN INDIAN JOURNAL OF MEDICAL AND PEDIATRIC ONCOLOGY.**
EXHIBIT P8	**TRUE COPY NEWS REPORT DATED 19.09.2022 FROM THE WEBSITE OF NOVARTIS, MANUFACTURER OF RIBOCICLIB.**
EXHIBIT P9	**TRUE COPY OF THE REPORT FROM THE WEBSITE OF U.S.**

	FOOD AND DRUG ADMINISTRATION.
EXHIBIT P10	TRUE COPY OF THE REPORT FROM THE WEBSITE CHEMOCARE.COM, AN ORGANISATION WORKING IN THE FIELD OF CANCER MEDICINE.
EXHIBIT P11	TRUE COPY OF THE E-REGISTER OF THE PATENT NUMBER 283133 DOWNLOADED FROM THE OFFICIAL WEBSITE OF THE 5TH RESPONDENT.
EXHIBIT P12	TRUE COPY OF THE RELEVANT PAGES OF THE COPY OF THE WORKING PAPER 490 AUTHORED BY SUDIP CHAUDHURI TITLED 'HOW EFFECTIVE HAS BEEN GOVERNMENT MEASURES TO CONTROL PRICES OF ANTI- CANCER MEDICINES IN INDIA?'PUBLISHED BY CENTRE FOR DEVELOPMENT STUDIES, THIRUVANANTHAPURAM, KERALA IN DECEMBER, 2019.
EXHIBIT P13	TRUE COPY OF THE FORM 27 PERTAINING TO THE PATENT NO. 283133 FOR THE YEAR 2018 DOWNLOADED FROM THE OFFICIAL WEBSITE OF THE 5TH RESPONDENT.
EXHIBIT P14	TRUE COPY OF THE FORM 27 PERTAINING TO THE PATENT NO. 283133 FOR THE YEAR 2019 DOWNLOADED FROM THE OFFICIAL WEBSITE OF THE 5TH RESPONDENT.
EXHIBIT P15	TRUE COPY OF THE FORM 27 PERTAINING TO THE PATENT NO. 283133 FOR THE YEAR 2020 DOWNLOADED FROM THE OFFICIAL WEBSITE OF THE 5TH RESPONDENT.
EXHIBIT P16	TRUE COPY OF THE FORM 27 PERTAINING TO THE PATENT NO. 283133 FOR THE YEAR 2021 DOWNLOADED FROM THE OFFICIAL WEBSITE OF THE 5TH RESPONDENT.
EXHIBIT P17	TRUE COPY OF THE REPORT PUBLISHED IN DECEMBER, 2019 BY U.S.FOOD & DRUG ADMINISTRATION, AUTHORED BY RYAN CONARD, RANDALL LUTTER WITH THE TITLE 'GENERIC COMPETITION AND DRUG PRICES: NEW EVIDENCE LINKING GREATER GENERIC COMPETITION AND LOWER GENERIC DRUG PRICES'.
EXHIBIT P18	TRUE COPY OF THE BREAST CANCER (AWARENESS AND FREE TREATMENT) BILL, 2017.

EXHIBIT P19	**TRUE COPY OF THE RELEVANT PAGES OF THE REPORT BY THE HIGH-LEVEL EXPERT GROUP ON UNIVERSAL HEALTH COVERAGE FOR INDIA.**
EXHIBIT P20	**TRUE COPY OF THE RELEVANT PAGES OF THE REPORT PREPARED BY ELLEN T HOEN FOR OXFAM INTERNATIONAL, WITH THE TITLE 'ACCESS TO CANCER TREATMENT - A STUDY OF MEDICINE PRICING ISSUES WITH RECOMMENDATIONS FOR IMPROVING ACCESS TO CANCER MEDICATION' (2014).**
EXHIBIT P21	**TRUE COPY OF THE SAME PAPER TITLED 'COMPULSORY LICENSES FOR CANCER DRUGS: DOES CIRCUMVENTING PATENT RIGHTS IMPROVE ACCESS TO ONCOLOGY MEDICATIONS?'.**
EXHIBIT P22	**TRUE COPY OF THE INFORMATION PUBLISHED BY THE PRESS INFORMATION BUREAU, MINISTRY OF COMMERCE AND INDUSTRY ON 19.12.2014.**
EXHIBIT P23	**TRUE COPY OF THE DRUGS (PRICES CONTROL) AMENDMENT ORDER, 2019 DATED 03.01.2019.**
EXHIBIT P24	**TRUE COPY OF THE NOTIFICATION DATED 27.02.2019 DOWNLOADED FROM THE OFFICIAL WEBSITE OF THE NATIONAL PHARMACEUTICAL PRICING AUTHORITY.**
EXHIBIT P25	**SEALED COVER**

RESPONDENTS' EXHIBITS

EXHIBIT R1(A)	**TRUE COPY OF THE MINUTES OF THE MEETING DATED 26.08.2022.**
EXHIBIT R1(B)	**TRUE COPY OF THE ORDER NO. P-24013(14)/1/2022-/PR-III DATED 07.10.2022.**
EXHIBIT-R8(A)	**TRUE COPY OF THE PRINTOUT OF THE PATENT CERTIFICATE OF ELI LILY IN 760 DATED 19.06.2018.**
EXHIBIT-R8(B)	**TRUE COPY OF THE COMPLETE SPECIFICATION OF IN 760**

	DATED 19.05.2011.
EXHIBIT-R8(C)	TRUE COPY OF THE E-REGISTER.
EXHIBIT-R8(D)	TRUE COPY OF THE ORDER DATED JUNE 19, 2020, IN CS COMM 183 OF 2020.
EXHIBIT-R8(E)	TRUE COPY OF THE PATENTS ACT, 1970 AT LENGTH IN RE: DISTRIBUTION OF ESSENTIAL SUPPLIES AND SERVICES DURING PANDEMIC, SUO MOTU WRIT PETITION (CIVIL) NO.3 OF 2021 (AIR-2022 PAGE NO.2356).
EXHIBIT-R8(F)	TRUE COPY OF THE WORKING STATEMENT FILED BEFORE THE INDIAN PATENT OFFICE. FOR INSTANCE, FOR THE YEAR 2020-21, ABEMACICLIB WORTH INR 4,33,00,000 WAS IMPORTED AND FOR THE YEAR 2021-22, ABEMACICLIB WORTH INR 21,32,00,000 WAS IMPORTED INTO INDIA. FORMS 27 AS FILED BEFORE THE INDIAN PATENT OFFICE.
EXHIBIT-R8(G)	TRUE COPY OF THE ONLINE ARTICLES, RESEARCH PAPERS BASED ON THE TUFTS CENTER FOR THE STUDY AND DRUG DEVELOPMENT ON DRUG DISCOVERY AND DEVELOPMENT, AND ARTICLES ON CLINICAL TRIALS FOR NEW DRUGS.
EXHIBIT R9(A)	TRUE COPY OF THE POWER OF ATTORNEY EXECUTED BY THE ADDITIONAL RESPONDENT NO.9 IN FAVOUR OF THE DEPONENT.
EXHIBIT R9(B)	TRUE COPY OF WHITE PAPER DATED 23.10.2018 ON BREAST CANCER LANDSCAPE IN INDIA.
EXHIBIT R9(C)	TRUE COPY OF US FOOD AND DRUGS ADMINISTRATION (USFDA) FOR ABEMACICLIB.
EXHIBIT R9(D)	TRUE COPY OF US FOOD AND DRUGS ADMINISTRATION (USFDA) FOR PALBOCICLIB.
EXHIBIT R9(E)	TRUE COPY OF US FOOD AND DRUGS ADMINISTRATION (USFDA) FOR RIBOCICLIB.
EXHIBIT R9(F)	TRUE COPY OF RESEARCH PAPER TITLED BREAST CANCER IN INDIA PRESENT SCENARIO AND THE CHALLENGES AHEAD, BY MEHROTRA R, YADAV K, DATED 24.03.2022.

EXHIBIT R9(G)	TRUE COPY OF PRESS RELEASE BY ADDITIONAL RESPONDENT NO.9 DATED 09.09.2022.
EXHIBIT R9(H)	TRUE COPY OF LIST OF ALL GENERIC PALBOCICLIC DRUG PRODUCTS AVAILABLE IN THE INDIAN MARKET AS ON 28.07.2023.
EXHIBIT R9(I)	TRUE COPY OF LIST OF ALL DRUGS APPROVED FOR TREATMENT OF BREAST CANCER AS AVAILABLE ON THE OFFICIAL WEBSITE OF NATIONAL CANCER INSTITUTE.
EXHIBIT R9(J)	TRUE COPY OF EXTERNAL MARKET DATA REPORT DATED 15.06.2023 PROVIDED TO NOVARTIS HEALTHCARE LIMITED BY COGNITREX CONSULTANTS PRIVATE LIMITED.
EXHIBIT R9(K)	TRUE COPY OF ADDITIONAL RESPONDENT NO.9S CURRENT PRICING CIRCULAR FOR RIBOCICLIB.
EXHIBIT R9(L)	TRUE COPY OF THE DRUGS (PRICES CONTROL) ORDER 2013 DATED 15.05.2013.
EXHIBIT R9(M)	TRUE COPY OF NATIONAL PHARMACEUTICALS PRICING AUTHORITY (NPPA) NOTIFICATION DATED 27.02.2019.
EXHIBIT R9(N)	TRUE COPY OF NATIONAL PHARMACEUTICALS PRICING AUTHORITY (NPPA) NOTIFICATION DATED 28.02.2020.
EXHIBIT R9(O)	TRUE COPY OF WEBSITE EXTRACTS OF ADDITIONAL RESPONDENT NO. 9 HIGHLIGHTING NOVARTIS POSITION ON ACCESS TO MEDICINES.
EXHIBIT R9(P)	TRUE COPY OF ADDITIONAL RESPONDENT 9S BROCHURE OF UMAANG PROGRAM.
EXHIBIT R9(Q)	TRUE COPY OF WEBSITE EXTRACTS OF KMSCL AND KARUNYA COMMUNITY SCHEME.
EXHIBIT R9(R)	TRUE COPY OF FORM 27 DATED 20.09.2022 FILED BY NOVARTIS FOR INDIAN PATENT NO.283133.
EXHIBIT R10A	A TRUE COPY OF THE LETTER DATED 19.04.2026 WRITTEN

BY DR.RAVI KANNAN TO THIS HON'BLE COURT.

ANNEXURE R13(A) TRUE COPY OF THE REPORT DATED 20.08.2026.

EXHIBIT R15(A) A TRUE COPY OF THE DISCHARGE SUMMARY ALREADY PRODUCED ALONG WITH MY AFFIDAVIT DATED 18.08.2026, FILED IN I.A. NO.1 OF 2026.

EXHIBIT R15(B) A TRUE COPY OF THE REPRESENTATIVE BILL DATED 16.09.2025 ISSUED BY THE MVR CANCER CENTRE AND RESEARCH INSTITUTE.

EXHIBIT R15(C) A TRUE COPY OF THE AFFIDAVIT BY MY TREATING DOCTOR DATED 30.08.2026.

EXHIBIT R15(D) A TRUE COPY OF THE RELEVANT PAGE OF THE NOVARTIS ANNUAL REPORT 2022.

EXHIBIT R15(E) A TRUE COPY OF THE RELEVANT PAGE OF THE NOVARTIS ANNUAL REPORT 2025.

RESPONDENTS' ANNEXURES

ANNEXURE I COPY OF THE PRESS RELEASE DATED 19.02.2016 FROM THE OFFICIAL WEBSITE OF PFIZER WITH THE TITLE 'PFIZER RECEIVES EXPANDED FDA APPROVAL FOR IBRANCE (PALBOCICLIB) IN HR, HER2- METASTATIC BREAST CANCER'.

ANNEXURE II COPY OF THE FDA APPROVAL NOTIFICATION DATED 03.03.2023 FROM THE OFFICIAL WEBSITE OF FDA WITH THE TITLE 'FDA EXPANDS EARLY BREAST CANCER INDICATION FOR ABEMACICLIB WITH ENDOCRINE THERAPY'.

ANNEXURE III COPY OF THE FDA APPROVAL NOTIFICATION DATED 17.09.2024 FROM THE OFFICIAL WEBSITE OF FDA WITH THE TITLE 'FDA APPROVES RIBOCICLIB WITH AN AROMATASE INHIBITOR AND RIBOCICLIB AND LETROZOLE CO-PACK FOR EARLY HIGH-RISK BREAST CANCER'

ANNEXURE IV **COPY OF THE STUDY TITLED 'REAL-WORLD EFFECTIVENESS COMPARISON OF FIRST-LINE PALBOCICLIB, RIBOCICLIB OR ABEMACICLIB PLUS ENDOCRINE THERAPY IN ADVANCED HR-POSITIVE/HER2-NEGATIVE BC PATIENTS: RESULTS FROM THE MULTICENTER PALMARES-2 STUDY', PUBLISHED IN ANNALS OF ONCOLOGY, VOLUME 36, ISSUE 7, 2025.**