Exhibit R1(b)

No. P-24013(14)/1/2022-IPR-III
DEPARTMENT FOR PROMOTION OF INDUSTRY & INTERNAL TRADE
MINISTRY OF COMMERCE & INDUSTRY
GOVERNMENT OF INDIA

Udyog Bhawan, New Delhi

Dated 07/10/2022

ORDER

Matter under consideration is the representaton dated 10th January 2022 filed Mrs. Saroja Radhakrishnan, a cancer patient, to Ministry of Health & Family Welfare MoHFW), Department of Pharmaceuticals (DoP), Department for Promotion of Industry and Internal Trade (DPIIT), and Ministry of Women and Child Development (MoWCD), for ensuring availability of the drug Ribociclib, a patented (Patent No. 283133) life-saving drug used in the treatment of Breast Cancer, at affordable price through for grant of compulsory license under section 92 or government use authorization under section 100 of the Patents Act, 1970.

2. In her representation, petitioner has submitted that she is a retired bank employee receiving monthly pension of Rs. 28,000/-, who is diagnosed with HER2-Negative Metastatic Breast Cancer. The monthly cost of the medicines for treatment works out to Rs. 63,480/-. The split-up details of which are as under:

1.Ribociclib - 58,140/-(including tax)
2. Latrazole - 1,027.75/- (including tax)
3. Zolendronic - 4,313/- (including tax)
Total - 63,480/-

3. The costliest medicine is Ribociclib, the price which alone comes to Rs. 58,140/- per month. Petitioner has claimed that the monthly pension of its family is spent on the treatment, as the crucial medicine prescribed for the treatment i.e Ribociclib is too expensive as it enjoys patent monopoly and is not manufactured in India. Petitioner has accordingly submitted that if the medicine is manufactured in India, the cost will come down substantially and will be affordable to persons like the petitioner.

4. Petitioner, hereafter referred to as Ext. P25, has also filed writ petition *WP(C) NO. 18999 OF 2022* (XXXX v. Union of India & Ors) before the Hon'ble High Court of Kerala at Ernakulam. Petitioner has prayed in the WP that DPIIT, 3rd respondent in the matter, maybe directed to consider her representation dated 10th January 2022, also forming part of her WP, and to take a reasoned decision on it. Taking cognisance of the matter, Hon'ble Court directed DPIIT vide its order dated 14th June, 2022 to pass a reasoned order on the representation of the petitioner.

5. In compliance of the Hon'ble Court's order dated 14th June 2022, the representation filed by the petitioner (Ext. P25) has been considered in detail by the

DPIIT. The patented drug under reference, with regard to which the representation was filed, is relevant from the perspective of health. Accordingly, the matter was referred to the MoHFW on 24th June 2022 for relevant facts and comments. The MoHFW vide email dated 30th July, 2022 and letter dated 28th August 2022 submitted comments and necessary facts on issues raised in the representation.

6. It may be noted that the drug mentioned in the representation Ribociclib is protected by Patent No. 283133, granted to Novartis and Astex Therapeutics on 05.05.2017, renewal fee has been paid till 21.05.2023, and the 20-year term of the patent will expire on 24.05.2027.

7. The petitioner in her representation has requested for grant of a compulsory licence or a government use authorization under the Patents Act, 1970 (Act) in respect of this patent. The issue of compulsory licence is to be dealt in accordance with section 92 of the Act, while the issue of government use authorization falls under section 100 of the Act.

8. As regards to the issue of compulsory licence, Section 92 of the Act states as follows:

> *"92. Special provision for compulsory licences on notifications by Central Government.—(1) If the Central Government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licenses should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the Official Gazette, and thereupon the following provisions shall have effect, that is to say—*
>
> *(i) the Controller shall on application made at any time after the notification by any person interested, grant to the applicant a licence under the patent on such terms and conditions as he thinks fit;*
>
> *(ii) in settling the terms and conditions of a licence granted under this section, the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.*
>
> *(2) The provisions of sections 83, 87, 88, 89 and 90 shall apply in relation to the grant of licences under this section as they apply in relation to the grant of licences under section 84.*
>
> *(3) Notwithstanding anything contained in sub-section (2), where the Controller is satisfied on consideration of the application referred to in clause (i) of sub-section (1) that it is necessary in—*
>
> *(i) a circumstance of national emergency; or*
>
> *(ii) a circumstance of extreme urgency; or*
>
> *(iii) a case of public non-commercial use, which may arise or is required, as the case may be, including public health crises, relating to Acquired*

Immuno Deficiency Syndrome, Human Immuno Deficiency Virus, tuberculosis, malaria or other epidemics,

he shall not apply any procedure specified in section 87 in relation to that application for grant of licence under this section:

Provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of section 87."

9. As regard to the issue of government use authorization, Section 100 of the Act states as follows:

"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 noncommercial use, the Government shall notify the patentee as soon as

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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 noncommercial basis, the goods 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."

10. From the above stated provisions under the Patents Act, 1970, it maybe noted that the necessary pre-requisite for invoking section 92 is that in respect of a patent, the Central Government should be satisfied that it is necessary that compulsory licenses should be granted in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use. In this regard MoHFW vide its OM dated 28th August 2022, in consultation with the Central Drugs Standard Control Organisation (CDSCO) and National Cancer Institute, AIIMS, Jhajjar, has clearly mentioned that no such conditions warranting action under Section 92 of the Patents Act exists at present for the drug Ribociclib.

11. The MoHFW in its email dated 30th July 2022 informed that the CDSCO has submitted the following in the matter:

"The Ribociclib Tablets 200 mg was approved for import and marketing after evaluation of clinical data in consultation with Subject Expert Committee (SEC). The SEC after deliberation opined that the drug is indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of post-menopausal women with the hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)- negative advanced or metastatic breast cancer which is an unmet medical need. CDSCO has granted import & Marketing permission to M/s. Sandoz Private Limited for Ribociclib 200 mg Tablets and to M/s. Pfizer Products India Pvt Ltd. for Palbociclib 75mg/100mg/125 mg Capsules. Further, CDSCO has granted manufacturing and marketing permission to M/s. Natco Pharma Ltd and M/s. MSN Laboratories Pvt. Ltd. for Palbociclib 75mg/100mg/125 mg Tablets."

12. In the same email dated 30th July 2022, MoHFW also shared submission of the National Cancer Institute, Jhajjar, an apex cancer Institute under AIIMS, New Delhi, as under:

"The Ribociclib is one of the group (CDK4/6 inhibitors) like Palbociclib (another drug, same group). Both the drugs are effective and safe in the management of Hormone positive, Her2 negative METASTATIC breast cancer and have been used as first line. The drawback is, both are expensive in the range of 58-75000 INR/ month. Through the support programme from the company itself, after 9 months, it is given free to patients till disease progression."

13. The MoHFW vide its OM dated 28th August 2022 has also informed that the CDSCO has been requested to examine the possibility of manufacturing the drug in India by companies already granted permission for manufacturing and marketing.

14. As regards to the affordability of drug, *'Ribociclib'*, the Department of Pharmaceuticals vide its OM dated 26th July, 2022 has informed that:

"With the aim to make the drugs affordable, National Pharmaceutical Pricing Authority (NPPA), an attached office of the Department of Pharmaceuticals (DoP), fixes the ceiling price of scheduled medicines specified in the First Schedule of the Drugs (Prices Control) Order, 2013 [DPCO] in accordance with the provision of DPCO. All manufacturers of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. A manufacturer is at liberty to fix the Maximum Retail Price (MRP) of a non-scheduled formulation, branded or generic, launched by it. However, as per the DPCO, 2013 the manufacturers of non-scheduled formulations are not allowed to increase the MRP of such formulations by more than 10% of maximum retail price during preceding twelve months.

There are 44 medicines prescribed as anti-cancer medicines in Schedule of DPCO, 2013. NPPA has fixed the ceiling prices of these 44 anticancer medicines comprising of 86 formulations. The list of 86 formulations along with applicable ceiling price (excluding GST) w.e.f. 01.04.2022 is placed at Annexure-A of DoP's OM dated 26.07.2022.

Further, vide order S.O. 1041[E] dated 27th February 2019, NPPA has put a cap on Trade Margin of 42 selected non-scheduled anti-cancer medicines (Annexure-B) on pilot basis under 'Trade Margin Rationalization' approach. It is mentioned that 'Ribociclib' is covered in the list of 42 selected non-scheduled drugs on which trade margin was capped at 30%. 'Ribociclib' is mentioned in S.O. 1041[E] dated 27th February 2019 at Sr. no. 31 in table attached as Annexure B of DoP's OM dated 26.07.2022.

Based on the requests received from the central procuring entities, where difficulties are being faced in procurement due to non-availability of Class I or Class II suppliers as per the PPO Order, a list of 209 drugs was published on the Department of Pharmaceuticals (DoP) website vide Public Notice dated 28.02.2022, seeking details of the local manufacturers available for these Drugs by 15.03.2022. The details received were examined by the Committee constituted by the DoP under the PPP-MII order. As per the committee's report, presently, there are no claimants for domestic manufacturing of the drug 'Ribociclib'."

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15. Upon a careful consideration of the representation and the response of the MoHFW, it is clear that the necessary pre-requisite for invoking section 92 – the satisfaction of the Central Government that it is necessary that compulsory licenses should be granted in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use – is not fulfilled in this case.

16. As far as the issue of government use authorization under section 100 of the Act is concerned, the MoHFW and DoP have clarified the factual position regarding the patented drug under reference. Apparently, in view of the factual position, the MoHFW and DoP have not made any request related to government use authorization under section 100 of the Act for consideration of the DPIIT. The issue is accordingly non-est.

17. The representation filed by XXXX (dated 10th January, 2022) is accordingly disposed of.

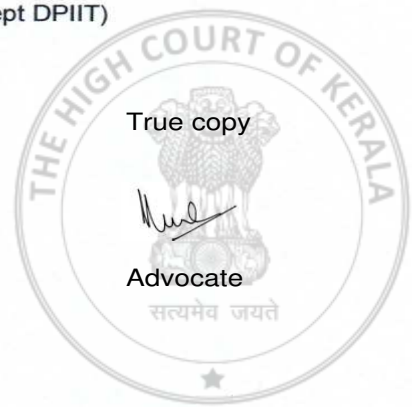
27/10/2022

(Sachin Dhania)
Deputy Secretary

To,

The Petitioner (XXXX)
PRA- 45A "Dwaraka" Palliparambukavu Road,
Tripunithura Ernakulam - 682301

Copy to:
All Respondents (Except DPIIT)



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Advocate

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