



2024:DHC:5969-DB



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\* **IN THE HIGH COURT OF DELHI AT NEW DELHI**  
+ **LPA 765/2024, CM APPL. 45324/2024 & CM APPL. 45325/2024**  
**COLOPLAST INDIA PRIVATE LIMITED** .....Appellant

Through: **Mr. R. Jawahar Lal and Ms. Meghna Kumar, Advocates**

versus

**UNION OF INDIA & ANR** .....Respondents

Through: **Mr. Anurag Ahluwalia, CGSC with Mr. Shivam Sachdeva (GP), Ms. Avshreya Pratap Rudy and Ms. Francita Mary, Advocates**

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Date of Decision: 08<sup>th</sup> August, 2024

**CORAM:**  
**HON'BLE THE ACTING CHIEF JUSTICE**  
**HON'BLE MR. JUSTICE TUSHAR RAO GEDELA**

### **JUDGMENT**

#### **MANMOHAN, ACJ: (ORAL)**

1. Present appeal has been filed challenging the impugned judgment dated 2<sup>nd</sup> July, 2024 passed by the learned Single Judge in W.P.(C) 6292/2022, whereby the writ petition filed by the Appellant seeking declaration that Surgical Bandages/Dressings do not fall within the scope of regulation/monitoring under Para 20 of the Drug Price Control Order, 2013 ("DPCO"), was dismissed in light of judgment of the Supreme Court in

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***Chimanlal Jagjivan Das Sheth vs. State of Maharashtra, AIR 1963 SC 665***, wherein the Apex Court held that surgical dressings would come under the purview of ‘Drugs’ under the Drugs & Cosmetics Act, 1940 (“**D&C Act**”).

2. Learned counsel for the Appellant states that the National Pharmaceutical Pricing Authority (“**NPPA**”) does not have the power to monitor and initiate action in respect of Surgical Dressings under Para 20 of the DPCO before 1<sup>st</sup> April, 2020, as only after 1<sup>st</sup> April, 2020, were all medical devices notified as ‘Drugs’ within the meaning of Section 3(b)(iv) of the D&C Act. He thus states that the learned Single Judge incorrectly held that Surgical Dressings were always covered under the definition of Section 3(b)(iv) of the D&C Act as ‘Devices’ and hence, they fall within the scope of Para 20 of the DPCO.

3. He submits that the ***Chimanlal*** judgment (supra) was rendered on 26<sup>th</sup> September, 1963, when Section 3(b) of the D&C Act contained only two sub-Clauses i.e. Section 3(b)(i) and (ii). He states that based on the un-amended definition of ‘Drugs’ under Section 3(b) the D&C Act, the Supreme Court held that the expression ‘substances’ used in Section 3(b)(i) of the D&C Act, would include “*things intended to be used for or in the treatment*” and thus Surgical Dressing would fall within the scope of the definition of ‘drugs’. He states that post 1983, were sub-sections (iii) and (iv) inserted. In this light, he submits that Surgical Dressings could not continue to be covered under the definition of ‘Drugs’ under Section 3(b)(i) of the D&C Act and thus the reliance upon the ***Chimanlal*** judgement (supra) was incorrect.



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4. He states that in terms of the amended definition (Section 3(b)(iv) of the D&C Act), 'Device' would fall within the ambit of the definition of 'Drugs', subject to the pre-condition that Respondent No. 1 ought to issue a Notification in the Gazette of India, prior to bringing any device within the definition of 'Drugs'.

5. He relies upon Office Order dated 9<sup>th</sup> July, 2014 issued by CDSCO, which unequivocally stated that other than the 14 notified medical devices (listed in the Office Order), other devices (non-notified medical devices), would not require any registration, license, permission or NOC for their import or manufacture, sale and distribution under the D&C Act. He states that Surgical Dressing was not one of the 14 notified medical devices notified as a 'Drugs' in the aforesaid Office Order dated 9<sup>th</sup> July, 2014.

6. Having perused the paper book, this Court finds that the issue as to whether surgical dressings would be covered under the definition of 'Drugs' or not, came up for consideration before the Apex Court in *Chimanlal* (supra), wherein the Apex Court held that absorbent cotton wool, roller bandages and gauze are substances within the meaning of 'Drugs' under Section 3(b)(i) of the D&C Act.

7. Admittedly, Section 3(b)(i) of the D&C Act has not been amended thereafter. Consequently, surgical dressings would continue to be covered under Section 3(b)(i) of the D&C Act as well as under Paragraph No.20 of the DPCO.

8. At this stage, learned counsel for the appellant states that though the learned Single Judge has clarified that the mode of calculation of charges



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would be in accordance with the judgment of this Court in *Union of India and Another v. Bharat Serums and Vaccines Limited*, 2023 SCC OnLine Del 7262, yet it has not remanded the matter to NPPA.

9. We find merit in the said submission. Accordingly, the matter is remanded to NPPA restricted to re-computation/re-calculation of charges in accordance with the judgment of this Court in *Bharat Serums* (supra).

10. With the aforesaid directions, the appeal stands disposed of.

**ACTING CHIEF JUSTICE**

**TUSHAR RAO GEDELA, J**

**AUGUST 8, 2024**

*Aj*