

UNION OF INDIA AND ORS.
v.
LEUKOPLAST PRIVATE LIMITED AND ORS.

JANUARY 25, 1994

[B.P. JEEVAN REDDY AND B.L. HANSARIA, JJ.]

Central Excises and Salt Act, 1944: Tariff Item 14-E of the First Schedule—Strips of surgical dressings—Containing pad medicated with Nitrofurazone in small quantity—Whether falls within the meaning ‘patent or proprietary medicine.’

The respondent-Company was manufacturing and selling strips of surgical dressings containing pads medicated with Nitrofurazone (0.125%). Whether this product was a ‘patent or proprietary medicine’ within the meaning of Tariff Item 14-E of the First Schedule to the Central Excise and Salt Act was gone into by the High Court at the instance of the respondent. It was contended by the respondent that the product was used merely for protecting a cut or wound from getting infected from dust and other substances, thus enabling the body system to cure itself. It was contended that product did not have any curative properties.

The appellant contended that Nitrofurazone used in the strip, was meant for curing/treating the wounds and, as claimed by the Respondent itself in its advertisements, the product was a medical preparation.

The High Court held that the said product was not a medical preparation and did not fall under Tariff Item 14-E of the First Schedule to the Central Excises and Salt Act. Against the said judgment of the High Court, appellant-Revenue preferred this appeal.

Dismissing the appeal, this Court

HELD: 1. The High Court was not correct in its reasoning that to call the product a medical preparation, Nitrofurazone must be atleast one per cent and since the product contained only 0.125 per cent it was not a medicine or medicinal preparation, in support of its reasoning, the High Court has relied upon a statement under the heading ‘Non-adherent Wound-contact Dressings’ Framycetin Sulphate Gauze (TULLE)

A Dressing' from a Text Book "The Pharmaceutical Codex" - Eleventh Edition - 1979, prepared and published by the Department of Pharmaceutical Sciences of the Pharmaceutical Society of Great Britain. A perusal of the matter shows that the said requirement is in the case of a gauze and not in the case of dressing or pad like the respondent's product. There is no other statement in the said CODEX, which says that in the case of a dressing pad like the one concerned herein, Nitrofurazone or other drug should be in a particular quantity. The said reason given by the High Court is, therefore, unsustainable. [346-H; 347-A-B]

C 2. Nitrofurazone is not applied to render the pad sterile; the pad is already rendered sterile and thereafter Nitrofurazone in the said small quantity is added. Therefore it cannot be said that the said small quantity of Nitrofurazone is applied to *preserve the sterility*. [347-C]

D 3. The High Court has traced the course of this litigation and the inordinate delays in deciding the matter. The respondent has been paying duty all the while under T.I. 68 till the Central Excise Tariff Act, 1985 came into force. *The difference of duty is very small*. Having regard to all these facts, no interference is called for under Article 136 of the Constitution of India. [347-F]

E CIVIL APPELLATE JURISDICTION: Civil Appeal No. 5449 (NM) of 1993.

From the Judgment and Order dated 2.8.1984 of the Bombay High Court in W.P. No. 174/B/1981.

F Joseph Vellapallaj, V.K. Verma, Dilip Tandon and C.V. Subba Rao for the Appellants.

A. Hidayatullah, Ravinder Narain, Vikram Nankani, Ms. Amrita Mitra and D.N. Mishra for the Respondents.

G The Judgment of the Court was delivered by

H B.P. JEEVAN REDDY, J. 1. The question in this appeal preferred by the Union of India against the decision of the Bombay High Court is whether the respondent's product, "Handyplast", is a 'patent or proprietary medicine' within the meaning of Tariff Item 14-E of the First Schedule to the Central Excise Act as it obtained at the relevant time. Tariff Item 14-E

read as follows:

Item No. 14E - PATENT OR PROPRIETARY MEDICINES

| Tariff Item No. | Description of Goods | Rate of Duty |
|-----------------|---|--------------------------------|
| 14E | PATENT OR PROPRIETARY MEDICINES not-containing alcohol, opium, Indian hemp or other narcotic drugs other than those medicines which are exclusively Ayurvedic, Unani, Sidha or Homeopathic. | 12.5 Percent <i>ad Valorem</i> |

Explanation 1 - 'Patent or Proprietary Medicines' means any drug or medicinal preparation, in whatever form, for use in the internal or external treatment of, or for the prevention of ailments in human beings or animals, which bears either on itself or on its container or both, a name which is not specified in a monograph in a Pharmacopoeia. Formulary or other publications notified in this behalf by the Central Government in the Official Gazette, or which is a brand name, that is a name or a registered trade mark under the Trade and Merchandise Marks Act, 1958 (43 of 1958), or any other mark such as a symbol, monogram, label, signature or invented words or any writing which is used in relation to that medicine for the purpose of indicating or so as to indicate a connection in the course of trade between medicine and some person, having the right either as a proprietor or otherwise to use the name or mark with or without any indication of the identity of that person."

Explanation II - (omited as unnecessary.)

2. The respondent as is a company engaged in the manufacture of strips of surgical dressings containing a pad medicated with nitrofurazone (0.125%) sold under the trade-name 'Handyplast'. A sample of the said product is placed before the Court as Exhibit- B. The following is the general description of such products, as set out by the High Court:

"Such elastic adhesive wound dressing consists of a fabric pad, comprising a piece of lint wrapped in muslin bandage, fixed to a

A rectangular piece of extension plaster so as to leave a margin of adhesive surface surrounding the pad. The elasticity of the plaster is unidirectional across the narrow width of the pad. The pad and adhesive margin are covered with a protector, which is removed before application. The pad is medicated with an antiseptic and dyed yellow, if necessary, with a non-toxic dye; the antiseptic and dye may be omitted if the dressing is supplied sterile."

3. Both parties agree that the product in question accords with the above description. The question is whether it is a 'patent or proprietary medicine' within the meaning of Tariff Item 14-E. The Explanation defines the expression "patent or proprietary medicines" to mean *inter alia* medicinal preparation, in whatever form for use in the external treatment of, or for the prevention of ailments in human beings which bears either on itself or on its container or both, a name which is not specified in a monograph in a Pharmacopoeia." The respondent's case is that the said product is used merely for protecting a cut or a wound from getting infected by dust and other substances, thus enabling the body system to cure itself. According to the respondent, it's product does not cure nor does it have any curative properties. On the other hand the case of Revenue is that had the product been supplied in a mere sterile form, the respondent's case could have been accepted but in this case the respondent adds a medicine namely Nitrofurazone after rendering the dressing sterile. The Revenue's case is that the Nitrofurazone is meant for curing/treating the cut or wound, as the case may be. In support of its case the Revenue relies upon the very advertisements issued by the respondent saying that it is a medicinal preparation.

4. The High Court has held in favour of the respondent mainly on two grounds viz., (i) for the said product to become a medicinal preparation, the Nitrofurazone must be at least one per cent; since it is only 0.125 per cent in the case of Handyplast it can not be called a medicine or medicinal preparation; and (ii) the said negligible amount of Nitrofurazone is applied "for an antiseptic purpose, that is to say, to make the said pad sterile." In support of the first proposition the High Court has relied upon a statement under the heading 'Non-adherent Wound- contact Dressings : FRAMYCETIN SULPHATE GAUZE (TULLE; DRESSING' from a Text Book "The pharmaceutical CODEX - incorporating the British Pharmaceutical Codex" - Eleventh Edition - 1979, prepared and published by

the Department of Pharmaceutical Sciences. The Pharmaceutical Society of Great Britain, we have perused the same and find that the said requirement is in the case of a gauze and not in the case of dressing of pad like the respondent's product. There is no other statement in the said CODEX, which says that in the case of a dressing pad like the one concerned herein, Nitrofurazone or other drug should be in a particular quantity. The said reason given by the High Court is, therefore, unsustainable.

5. Coming to the other ground given by the High Court we find ourselves equally unable to agree. The Nitrofurazone is not applied to render the pad sterile; the pad is already rendered sterile and thereafter Nitrofurazone in the said small quantity is added. Before us Shri Hidayatullah, learned counsel for the respondent, sought to contend that the said small quantity of nitrofurazone is applied to *preserve the sterility*; but this is not the ground assigned by the High Court, nor is any text book cited by learned counsel to support his contention conclusively.

6. Even though we are not satisfied with the reasoning of the High Court, we are of the opinion that no interference is called for in the particular facts and circumstances of the case. The relevant facts relating to the dispute concerned herein have been stated in the opening paragraphs of the Judgment of the High Court, which establish that the proviso to Section 11-A may not be attracted to this case. The High Court has traced the course of this litigation and the inordinate delays in deciding the matter. The Respondent has been paying duty all, the while under T.I.68 till the Central Excise Tariff Act, 1985 came into force. *The difference of duty is very small*. Having regard to all the above facts, we do not think this is a fit case for interfering under Article 136 of the Constitution.

The appeal is accordingly dismissed subject to the findings recorded hereinbefore. No orders as to cost.

G.N.

Appeal dismissed.