(2011) 10 DEL CK 0127

In the Delhi High Court

Case No : Writ Petition (C) 5836 of 2011 and C.M. No. 11860 of 2011

Vishal Surgical Equipment Co. — APPELLANT

Vs

The Drug Controller General of India and Another — RESPONDENT

Date of Decision : 20-10-2011

Acts Referred:
Drugs and Cosmetics Act, 1940 — Section 10, 10A, 3, 7(3)
Drugs and Cosmetics Rules, 1945 — Rule 123, 43

Citation : (2011) 10 AD 388 : (2011) 184 DLT 343

Hon'ble Judges : Vipin Sanghi, J

Bench : Single Bench

Advocate : Suhail Dutt, with Ms. Ekta Kapil, Ms. Anubha Singh, Ms. Rashi and Ms. Atishree Sood, for the Appellant; Sachin Datta, CGSC., for the Respondent

Final Decision : Allowed

Judgement

Vipin Sanghi, J.—''Rule''.

2. With the consent of parties, I have heard learned counsel for the parties on the basis of the pleadings on record at length, and proceed to dispose of the present petition at this stage itself.

3. The petitioner has preferred this petition to seek issuance of a writ of certiorari to seek quashing/setting aside of the order dated 05.08.2011 passed by the Drug Controller General of India/respondent No. 1. A mandamus is sought against the respondent No. 1 for release of the goods of the petitioner, which were seized by him. The petitioner also seeks a declaration that Potassium Monopersulphate (RelyOn Virkon Powder) is not a "drug" within the meaning of that expression as used in the Drugs and Cosmetics Act, 1940 (The Act) and Drugs and Cosmetics Rules, 1945 (The Rules). The petitioner also seeks quashing of the letter dated 24.05.2011 issued by the Assistant Drug Controller to the Director General of Armed Forces Medical Sciences (India), whereby the Director General of Health Services, acting through the Assistant Drug Controller (I), directed the Director General of Armed Forces Medical Services (India) not to

dispose of the drug imported by the petitioner namely Virkon (Potassium Monopersulphate Powder) in their hospitals. The petitioner also seeks a restrain against the respondent from taking any action in pursuance of impugned order dated 05.08.2011, and a declaration that the petitioner does not require any license to import Potassium Monopersulphate (RelyOn Virkon powder).

4. The petitioner is an importer of the aforesaid product. It is not in dispute that the petitioner imported the said product earlier by obtaining a license which was valid between 17.07.2008 to 30.06.2010. After the expiry of the said license, the petitioner did not apply for a fresh import license, but continued to import the product. According to the petitioner, the Ministry of Defence vide communication dated 02.04.2007 sought clarification "whether Potassium Monopersulphate Powder 1% is a drug item and is covered under Drugs & Cosmetic Act or it is a non-drug item". The Assistant Drug Controller Mr. M. Mitra on 09.04.2007 clarified that the said product is not a "drug" within the definition of that expression as used in the Act. The petitioner had also moved an application on 17.03.2004 to the Drug Controller General of India claiming that the said product is not a "drug", and had sought "No Objection Certificate" to allow its import into India as, according to the petitioner, the said product did not come within the purview of the Act and, therefore, no registration was required. According to the petitioner, this representation was not responded by the respondent at all, one way or another.

5. The petitioner was issued a show-cause notice dated 29.06.2011 on the allegation that the petitioner had unauthorisedly imported the product, which was a drug. The petitioner was asked to show-cause as to why prosecution should not be launched against the petitioner for violation of the provisions of the Act and the rules framed thereunder. The petitioner challenged the said show-cause notice by filing W.P.(C.) No. 4808/2011. This petition was disposed of by the order of this Court dated 13.07.2011. The Court recorded the respondent''s submission that the said show-cause notice be also construed as a notice on the entire matter including on the issue as to whether any violation has been committed by the petitioner or not. The writ petition of the petitioner was directed to be treated as representation/reply to the show-cause notice. The petitioner was directed to appear for hearing on 22.07.2011 and it was directed that an order be passed on or before 05.08.2011. The present petition has now been filed as the respondent No. 1 has passed the impugned order dated 05.08.2011 holding that the product Potassium Monopersulphate powder 1% is a "drug" within the definition of that expression as used under the Act, and has directed initiation of further legal action against the petitioner.

6. The first submission of the learned senior counsel for the petitioner is that the impugned order is totally non-speaking inasmuch, as, none of the submissions of the petitioner on the issue that the aforesaid product namely Potassium Monopersulphate powder 1% is not a "drug" within the meaning of that expression as used in the Act have been dealt with. There is no consideration of

the said issue by reference to the statutory provisions and the notifications issued thereunder. The order has been passed only on the premise that earlier, the petitioner had obtained registration prior to import, by itself treating the product as a "drug". It is also submitted that even though the hearing was held before Mr. Bangaru Rajan (DDCI-Import and Registration), Dr. D. Roy (DDCI - CDSCO North Zone Ghaziabad) and Mr. Arvind Kukreti (ADCI - Import and Registration), the impugned order has been passed by Dr. Surinder Singh, Drugs Controller General (India), who was not even present on the date of hearing. It is argued that on this short ground, the impugned order is liable to be set aside.

7. Learned senior counsel for the petitioner Mr. Suhail Dutt submits that merely because the petitioner - who is an importer and the manufacturer of the said product may have, under a mistaken belief, treated the said product as a "drug" and applied for license/registration under the Act, it does not mean that the said product can be classified as a "drug". It is argued that there is no estoppel against the law.

8. It is further submitted that the expression "drug" as used in the Act has a statutory definition and the issue whether or not the product in question is a "drug" has to be decided in the light of the statutory definition, and not merely because earlier the same has been considered to be a "drug" by the petitioner or the manufacturer. According to the petitioner, the product in question which is imported under the brand/trade name "RelyOn Virkon Powder" is a high level surface disinfectant. The said product does not fall within the definition of the expression "drug" as contained in Section 3(b)(i) which defines "drug" to include "all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes". According to the petitioner, since the said product is not used either internally or externally on human-beings or animals, the same is not covered by Section 3(b)(i) of the Act. It is further submitted that the said product is not covered by the expression "drug" within the meaning of that expression u/s 3(b)(ii) which defines "drug" to include "such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette".

9. Mr. Dutt submits that the notification published by the Central Government in the Official Gazette bearing No. 1-20/60-D dated 03.06.1961, as amended, u/s 3(b)(ii) specifies as drugs, inter alia:

(1) Disinfectant fluids made from Coaltar Oils, Coaltar acids or similar acids derived from petroleum with or without hydrocarbons.

(2) Disinfectant fluids made from synthetic or naturally occurring substances

other than those mentioned in (1) above by virtue of their composition possessing disinfectant properties or with claim to possess disinfectant properties.

(Emphasis supplied)

10. Mr. Dutt submits that the product in question is not made from Coaltar Oils, Coaltar acids or similar acids derived from petroleum with or without hydrocarbons. It is also not a "fluid", as what is imported is a powder, and is not made from synthetic or naturally occurring substances. It is, therefore, argued that the product in question does not fall within the definition of "drug" as contained in Section 3(b)(ii).

11. He further submits that even if it is considered to be a "fluid", the same is not made from synthetic or naturally occurring substances. Mr. Dutt submits that on the basis of complaint made by a competitor, the Assistant Drug Controller (I) issued the impugned communication dated 24.05.2011 to the Director General of Armed Forces Medical Services (India) directing it not to dispose of the product in question in their hospitals. The Ministry of Defence has, on the basis of the said compliant, called upon the command hospitals to avoid business activities in relation to the said product. He submits that on account of the aforesaid act, the petitioner''s business is diminishing.

12. Mr. Dutt further submits that even if the product in question were to be categorized as a "drug", by virtue of Rule 43 of the Rules, the same is exempt from the provisions of Chapter III of the Act and the Rules made thereunder, to the extent and subject to the conditions specified in Schedule-D. Schedule-D exempts in relation to the substances not intended for medical use, "all provisions of Chapter III of the Act and Rules thereunder subject to the condition that if the substance is imported in bulk, the importer shall certify that the substance is imported for non-medical uses, and if imported otherwise than in bulk, each container shall bear a label indicating that the substance is not intended for medicinal use or is intended for some purposes other than medicinal use or is of commercial quality."

13. Mr. Dutt submits that a perusal of the counter-affidavit filed by the respondent shows that the respondent has sought to justify the impugned order on various grounds, which are not even contained in the impugned order dated 05.08.2011. He submits that it is not open to the respondents to improve upon the impugned order, or defend the same by resort to other submissions and grounds, which are not to be found in the said order. In this regard, he places reliance on decision of this Court in Indian Oil Corporation Ltd. Vs. SPS Engineering Ltd., , which, in turn, relies on various decisions of the Supreme Court.

14. On the other hand, the submission of Mr. Sachin Datta, learned Standing Counsel, is that the product in question is a "drug" not only within the ambit of Section 3(b)(i) but also Section 3(b)(ii) of the Act. He submits that it is covered by the aforesaid notification No. 1-20/60-D dated 03.06.1961, as amended,

inasmuch as it is disinfectant "fluid" made from synthetic or naturally occurring substances. He submits that the product in question, though imported in powder form, cannot be used as such and is required to be converted into "fluid" state by adding water in the prescribed proportion. In this regard, he has referred to the catalogue issued by the manufacturer "Dupont", which prescribes the manner in which the 1% solution is to be prepared. He further submits that the stand of respondent No. 1 in the counter-affidavit is that the product of the petitioner may be used as a synergistic, broad spectrum virucide, fungicide and bactericide in animal containment areas and for veterinary surgeries as well as for treatment of Pseudomonas Aeruginosa, E.coli, Listeri Monocytogenes, Staphylococcus Aureus, Salmonella typhimuriam and infectious Salmon Anaemia virus.

15. He submits that there is no rejoinder filed by the petitioner to controvert the aforesaid stand of the respondent. He submits that on account of the aforesaid possible use, the product in question is liable to be categorized as a "drug" within the meaning of that expression defined in Section 3(b)(i). Mr. Datta further submits that the petitioner has no locus standi, and it does not lie in the mouth of the petitioner, to contend that product is not a "drug" when the manufacturer of the product itself treats itself same as a "drug". He submits that the manufacturer has obtained the requisite license under the Act and the rules framed thereunder by treating the same as a "drug".

16. The petitioner has specifically averred in para 2(e) of the petition that the hearing was held before three officers, namely Mr. Bangaru Rajan (DDCI-Import and Registration), Dr. D. Roy (DDCI - CDSCO North Zone Ghaziabad) and Mr. Arvind Kukreti (ADCI - Import and Registration), but the impugned order has been passed by Dr. Surinder Singh, Drugs Controller General (India), who was not even present on the date of hearing. In their counter-affidavit, the respondents have not specifically denied this categorical and direct averment of the petitioner. In fact, this averment has not been denied even indirectly or impliedly. Therefore, I am inclined to accept this submission of the petitioner, which has gone unrebutted.

17. It is well-settled that the authority, who is empowered to pass order alone should grant the personal hearing (in all such cases where personal hearing is granted), and that he alone should pass the order. It is elementary that personal hearing cannot be granted by one set of officers and the order passed by another officer, as done in this case. The grant of personal hearing is not an empty formality. The purpose of such a hearing is to enable the party being heard to communicate his submissions to the person granting the hearing so that there is an effective discussion and doubts, if any, are clarified and all questions that may be raised by the person granting the hearing are answered. If the procedure, as adopted by the Drugs Controller General (India) were to be accepted, there was no purpose of granting a personal hearing to the petitioner. It is clear that the impugned order dated 05.08.2011 passed by Dr. Surinder Singh, Drugs Controller General (India) suffers from non-application of mind. He has not

applied his mind and considered the oral submissions made by the petitioner during the personal hearing, as he was not even present when the said hearing was held. On this short ground, the impugned order dated 05.08.2011 is liable to be quashed and set aside.

18. A perusal of the impugned order also shows that the Drugs Controller General (India), while passing the impugned order, has failed to even advert to the arguments raised by the petitioner in response to the show cause notice. The submission of the petitioner that the product in question is not a "drug" because the same does not fall within the meaning of the expression "drug" used in Section 3(b)(i) or 3(b)(ii) has not at all been considered. The only basis for the finding returned in the impugned order that the product in question is a "drug" is that the petitioner himself had obtained a license for import under the Act at an earlier point of time; that the manufacturer has also obtained a license/ registration and; that the petitioner had not raised the issue that the product is not a "drug" at an earlier point of time and the said issue was raised only when the petitioner started to import the product without a license and was issued a show cause notice.

19. The approach of the Drugs Controller General (India) while passing the impugned order is patently laconic. He has conveniently avoided to examine in depth, as was expected of him, the issue whether the product in question is a "drug" by reference to the definition of the term "drug" contained in Sections 3(b)(i) & 3(b)(ii) of the Act.

20. The mere fact that the petitioner had earlier obtained a license for import of the product in question, or that the manufacturer has obtained the registration/ license, is neither here nor there. The determination of the issue whether the product is a "drug" or not within the meaning of that expression as used in the Act, depends entirely upon the examination of the issue whether the product satisfies the conditions contained in Section 3(b)(i) and/or 3(b)(ii) of the Act. It is well-settled that there is no estoppel against the law. Therefore, even if the petitioner or the manufacturer may have obtained license/registration earlier, under either a mistaken belief, or simply to avoid getting embroiled in a dispute with the respondents, that would not have any bearing on the determination of the issue whether the product in question is a "drug" or not.

21. In this regard, I may only refer to the judgment of the Supreme Court in the case of Kalidas Dhanjibhai Vs. The State of Bombay, . In this case, the appellant was the owner of a small establishment which employed three workers. The question which arose for consideration was whether the appellants concern was a "shop" within the meaning of section 2(27) of the Bombay Shops and Establishments Act, 1948. The Supreme Court came to the conclusion that the establishment of the appellant was not a shop. While setting aside the judgment of the Bombay High Court, the Supreme Court in para -11 held as follows:

11. The learned High Court Judges were influenced by matters which we consider

inconclusive. The appellant applied for registration under the Bombay Act and in the statement made u/s 7 he called his establishment a "workshop" and described the nature of his business as a "factory". The learned Judges considered that this imported an admission that his establishment was a "shop" because of the use of the word "shop" in "workshop". This might have raised an inference of fact against the appellant had nothing else been known but when the facts are fully set out as above and admitted, the appellant''s opinion about the legal effect of those facts is of no consequence in construing the section. No estoppel arises. The appellant explained that the matter seemed doubtful, so, to be on the safe side and avoid incurring penalties for non-registration should it turn out that his concern was hit by the Act, he applied for registration. It is to be observed that though he applied on 12th April, 1949, he was not registered till 4th May, 1950, and the certificate was not given to him till 8th January, 1951. The present prosecution was launched on 4th April, 1951. Government itself seems to have been in doubt. However, that is neither here not there. What we think was wrong was placing of the burden of proof on the appellant, in a criminal case, because of a so-called admission. The learned High Court Judges also advert to the fact that though the appellant''s concern was registered as a "shop" he made no protest and did not have recource to section 7(3) of the Act.

22. This Court, in its order dated 13.07.2011 passed in W.P.(C.) No. 4808/2011, had directed that the said writ petition be treated as a representation/reply to the show cause notice. I may only refer to the grounds (h), (i), (j), (l), (m), (n) & (o) of the grounds taken in the earlier writ petition, which elaborately set out the petitioner''s case. These grounds read as follows:

H. For that even though to the knowledge of the Respondents, no Drug Import License was mandatory for import of "Virkon" as it is neither a drug under the Act and/or in any event exempt from an import and/or sale license as it is brought under Rule 43 read with Schedule D and Rule 123 read with Schedule K of the Drugs and Cosmetics Rules, 1949 (hereinafter referred to as the "Rules"), yet the Respondent No. 1 has arrived at a perverse finding that the petitioner has imported 2 consignments of "Virkon" without an import license and has issued a show cause on the question of punishment only.

I. for that the Show Cause Notice holds Rely On TM Virkon? powder imported by the Petitioner is a drug. It is submitted that Rely On TM Virkon? powder powder is not a drug as there is no notification passed by the Central Government in any official gazette holding Rely On TM Virkon? powder to be a drug. Further, there is no reason or instance cited by the Respondent No. 1 for the reason which Rely On TM Virkon? powder can be held to be a drug. It is submitted that the Respondent No. 1 own its own and without any justification has gone ahead and treated Rely On TM Virkon? powder as a drug.

J. For that the Show Cause Notice fails to consider the clarification dated 09.04.2007, issued by the Assistant Drug Controller (I) stating that Rely On TM Virkon? powder is not mentioned is any official monograph and is not a drug

item. It is submitted that the Respondents have been changing its stands to non-suit the Petitioner. In the year 2001, a No Objection Certificate was given by Assistant Drug Controller (I) stating that Directorate has no objection for importing of Rely On TM Virkon? powder so far as the Act and the Rules framed thereunder are concerned. The said act of changing stands by Respondents to suit vested interest is arbitrary and malafide, which ought not to be allowed.

K. xxxx

L. For that the Respondents failed to consider that the Petitioner does not need any drug import licence under the At or the Rules to import Rely On TM Virkon? powder in India. It is submitted that Rely On TM Virkon? powder is not a drug and does not attract the provisions of the Act and Rules. Therefore, Rely On TM Virkon? powder can be imported into India by the Petitioner, without obtaining any drug import license.

M. For that the Respondents failed to consider that Rely On TM Virkon? powder is not treated as drug worldwide but the same is treated as a chemical disinfectant. It is submitted that Rely On TM Virkon? powder is not treated as a drug in various countries such as USA, UK, European Union Countries, Germany, France, Spain, Italy; Poland and Belgium and Asia Pacific countries such as China, Australia, Indonesia, Singapore, Thailand and Taiwan.

N. For that the Respondents failed to consider that Rely On TM Virkon? powder is a disinfectant which is used in hospitals environment such as operation theaters, ICU''s, Wards for disinfecting floors, walls, table tops, surfaces trolleys. Rely On TM Virkon? powder is not used to affect the structure of human bodies or animals. It is not used for destruction of Vermin or insects which causes diseases in human beings or animals. It is not used for any medicinal use.

O. For that the Respondents failed to consider that Rely On TM Virkon? powder, imported by the Petitioner in India, is not used for manufacturing of and medicine. It cannot be applied on human beings or animals, directly or indirectly, for any treatment or to cure any disease in them. Further, the caution warning displayed by the Petitioner on its packaging clearly shows that the Rely On TM Virkon? powder is not to be applied on human beings or animals.

23. None of these aspects have been considered by the Drugs Controller General (India) in the impugned order.

24. I, therefore, agree with the submission of the learned senior counsel for the petitioner that the impugned order is a non-speaking order inasmuch, as, it does not discuss the submissions of the petitioner, which were to be found in the petitioner''s earlier writ petition.

25. The expression "drug" as used in the Act has been given a statutory definition. Therefore, to find out whether the product in question is a "drug" or not, it is necessary to examine whether it falls in one or more of the clauses (i) to (iv) of Section 3(b) of the Act. According to the respondent, the product in

question is "drug" as it falls in Clause (i) & (ii) of Section 3(b), which have already been extracted hereinabove.

26. I may also note at this stage itself, that there is merit in the petitioner''s submission that the impugned order has to be tested on its own strength and cannot be supplemented by additional material, either in the form of affidavit or otherwise. The endeavour of the respondents to justify the impugned order, which holds that the product in question is a "drug", for reasons which are not contained in the impugned order, but are set out in the impugned order is, therefore, impermissible in the light of the judgment of this Court in SPS Engineering Ltd. (supra). In any event, I proceed to examine the issue whether the product in question is a "drug" or not, since both sides have made their respective submission on this issue as well.

27. Mr. Datta submits that the product is "drug" u/s 3(b)(i) as, according to the respondents, the said product may be used as synergistic, broad spectrum virucide, fungicide and bactericide in animal containment areas and for veterinary surgeries as well as for treatment of Pseudomonas Aeruginosa, E.coli, Listeri Monocytogenes, Staphylococcus Aureus, Salmonella typhimuriam and infectious Salmon Anaemia virus. Pertinently, this assertion of the respondents has no basis. Even the respondents do not make a categorical assertion that the product in question is capable of being used for the said purpose. It is merely claimed that "it may be used" for the purpose claimed by the respondents. There is no medical literature, or literature obtained from the manufacturer to support this contention. It is obvious that if the product could be used for the purposes as claimed by the respondents, the same would have been reflected in the manufacturer''s catalogue. A manufacturer, to market its product, would give all possible uses to which its product can be put. Neither there is any literature nor any scientific evidence or report, to back the claim of the respondents that the product in question may be used in the manner claimed by the respondents, as aforesaid. On the contrary, the petitioner has produced the literature in relation to the said product as published by the manufacturer "Dupont". As per the said literature, it appears that the product is a disinfectant, cleaning agent and is described by the manufacturer as a "high level surface disinfectant". The manufacturer also prominently notifies the users of the product as follows:

Irritating to skin

Risk of serious damage to eyes

Harmful to aquatic organisms

Do not breathe dust

Keep out of reach of children

Avoid contact with skin and eyes

In case of contact with eyes, rinse immediately with plenty of water and seek

medical advice

Wear suitable clothing, gloves and eye/face protection

This material and its container must be disposed of as hazardous waste

28. I, therefore, reject the submission of Mr. Datta that the product in question is classifiable as a "drug" by resort to Section 3(b)(i) of the Act. The submission of Mr. Datta that the product falls in Section 3(b)(ii) as it is intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, needs to be examined in the light of the Official Gazette notified by the Central Government as, for the application of Clause (ii) of Section 3(b), it is necessary that the substance is so notified for it to be classified as a "drug". It is not that every substance which is used for destruction of vermin or insects which causes disease in human beings or animals ipso facto can be classified as a drug within the meaning of section 3(b)(ii) of the Act. It is equally necessary that the said substance is notified in the official gazette by the Central Government. The notification, insofar as it is relevant, has been extracted hereinabove. Admittedly, the product in question is not made from Coaltar Oils, Coaltar acids or similar acids derived from petroleum with or without hydrocarbons.

29. The only issue is: whether the product in question can be called as a disinfectant "fluid" made from synthetic or naturally occurring substances? The notification consciously uses the words "disinfectant fluids". It does not use the expression only "disinfectant" or "disinfectant fluids or powders". The expression "fluid" is defined in the Shorter Oxford English Dictionary as: "(1) flowing or moving readily, not solid or rigid. It means a fluid substance; a liquid, a gas; esp. a liquid preparation having a specified purpose".

30. The product in question, as imported by the petitioner, admittedly, is not in fluid or liquid state. It is imported in powder state and sold as such to the customers. It is the customers who add water to it in the proportion prescribed by the manufacturer to prepare the 1% solution, i.e., fluid. The manner of preparation prescribed in the catalogue of the manufacturer reads as follows:

Preparation:

To prepare a 1% solution

Using the figures in the table, prepare the relevant volume of luke-warm water.

RelyOnTMVirkon?

WATER

Add the appropriate amount of RelyOnTMVirkon? and stir until the powder has dissolved, leaving a clear pink solution.

10g

1 litre

50g

5 litre

100g

10 litre

31. The product in question, therefore, in my view, cannot be called "a disinfectant fluid" and would, therefore, not fall within the scope of the notification issued by the Central Government u/s 3(b)(ii) of the Act. Merely because the product can be used in fluid/liquid form upon water being added to it, it does not mean that the product when imported in powder state can be considered to be "a disinfectant fluid". Learned counsel for the respondent has not shown any authority in support of the proposition that because the powder has necessarily to be converted into a liquid by addition of water before its use, the powder should be considered to be fluid for the purposes of the aforesaid notification.

32. I may also note that, according to the petitioner, the product is not made from synthetic or naturally occurring substances other than those mentioned in Clause (i), i.e. Coaltar Oils, Coaltar acids or similar acids derived from petroleum with or without hydrocarbons. However, the petitioner has not produced any material in support of this submission and, therefore, I do not consider it necessary to go into the said issue.

33. Even if the submission of Mr. Datta, that the product in question is capable of being used only as a fluid and, therefore, the same should be considered as "disinfectant fluid" falling within the scope of the aforesaid notification 1-20/60-D, as amended, issued u/s 3(b)(ii) of the Act were to be accepted, in my view, the said submission of Mr. Datta has been successfully met by the petitioner whose alternative submission is that, in any event, by virtue of Rule 43 read with Schedule D, the product in question is exempt from the provisions of Chapter III of the Act and the rules made thereunder to the extent, and subject to the conditions specified in that Schedule. Entry at Sl.No. 1 of Schedule D deals with class of drugs which are substances not intended for medical use. I have already concluded, the product in question cannot be called a substance which is intended for medical use. Therefore, the product in question is covered by Entry at Sl.No.1 of Schedule D.

34. It is not the respondents" case that the product in question, as imported by the petitioner, is claimed by the petitioner, to have been imported with the intention of being put to medical use. The product is a surface disinfectant and is intended for a purpose other than medical use. The import is of a commercial quality inasmuch, as, it has been imported and supplied by the petitioner to various defence organizations. Consequently, the product in question is exempt from application of all provisions of Chapter III of the Act. The prohibition against import of certain drugs and cosmetics, and against import of drugs and

cosmetics in public interest is contained in Sections 10 and 10A of the Act which fall in Chapter III of the Act. Consequently, the import of the product in question, even if it is classified as a "drug" falling in Section 3(b)(ii), is not subject to the obtainment of prior license, as its import is for non-medical use; is not intended for medical use, and, is for a purpose other than medical use, and the import is of commercial quality.

35. For all the aforesaid reasons, I allow this writ petition and make the "Rule" absolute. The impugned order dated 05.08.2011 passed by Dr. Surinder Singh, Drugs Controller General (India), is hereby quashed. Respondent No. 1 is directed to forthwith release the goods of the petitioner, which have been seized. I declare that Potassium Monopersulphate, which is imported, is not a "drug" within the meaning of that expression as used in the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. The letter dated 24.05.2011 issued by the Assistant Drug Controller to the Director General of Armed Forces Medical Sciences (India), is consequently quashed.

36. The petitioner is entitled to costs quantified at Rs.25,000/- to be paid within four weeks.

