

(2016) 09 BOM CK 0051

In the Bombay High Court

Case No : Criminal Application No. 3956 of 2015

Chutararam S/o Nemaram Gehlot

APPELLANT

Vs

State of Maharashtra

RESPONDENT

Date of Decision : 28-09-2016

Acts Referred:

Drugs and Cosmetics Act, 1940 — Section 33

Drugs and Cosmetics Rules, 1945 — Rule 138, 142, 148

Citation : (2016) 3 AIRBomRCri 679 : (2016) ALLMRCri 5135 : (2017) 1 BomCR(Cri) 772 : (2016) 6 MhLJCrI 748

Hon'ble Judges : V.K. Jadhav, J.

Bench : Single Bench

Advocate : Shri V.J. Dixit, Senior Counsel i/b Mr. H.H. Padalkar, A.P.P, for the Applicant; Mr. A.R. Kale, Advocate, for the Respondent No. 3

Final Decision : Allowed

Judgement

V.K. Jadhav, J.—Rule. Rule made returnable forthwith. With the consent of learned counsel for respective parties, heard finally at admission stage.

2. The petitioner original accused is seeking quashment of criminal proceeding bearing R.C.C. No. 487 of 2006 pending before the Chief Judicial Magistrate, Jalgaon.

3. Brief facts, giving rise to the present application, are as under:-

a) The applicant is proprietor of "Prem Mehendi Center" having its office at Plot Nos. 2 and 3 as detailed in the title cause at Jalgaon, Maharashtra. The said establishment "Prem Mehendi Center" is a small manufacturer of Heena/Mehandi Powder and Mehendi cone products on household basis. The applicant No. 1 has started the business at Jalgaon in the year 2006 and also engaged few persons on daily wages basis. The applicant No. 1 had also obtained manufacturing cosmetic licence for Mehendi products at the said premises under the provisions of Drugs and Cosmetics Act 1940 (hereinafter for the sake of brevity referred to

as the "Act of 1940") and also renewed the same regularly.

b) Respondent No. 1 on 22.5.2006 visited the premises of "Prem Mehendi Center" at Jalgaon. The applicant No. 2 was present at the time in the said premises. Respondent No. 1 Drug Inspector had taken two samples of Mehendi cone and three samples of Mehendi powder from the premises of the "Prem Mehendi Center", Jalgaon. Those samples were further sent to the Government analyst for analysis and to ascertain whether the said product contains any Para Phenyl Diamine (PPD) or Ammonia. However, after detail analysis by the Government Analyst it was found that the said samples were of standard quality and does not contain any hazardous or harmful substance for human use. The said samples also did not contain any material/chemical etc. However, according to the respondent Drug Inspector, the said samples did not contain labels in the prescribed manner and there was no valid licence at the relevant time. Consequently, the respondent Drug Inspector filed a complaint against the applicants original accused which is numbered as R.C.C. No. 487 of 2006. The learned Judge of the trial court was pleased to issue process by order dated 7.10.2006 for the offence punishable under sections 18(a) (ii) and Section 17(c) r.w. Rules 146, 148 and Section 18(c) of the Drugs and Cosmetics Act 1940 and the Rules thereunder and punishable under Section 27- a (ii) of the Act of 1940. Hence, this Criminal Application.

4. Learned counsel for the applicants submits that, no manufacturing licence is required for manufacture of the Mehendi products under the provisions of the Act of 1940. Therefore, there is no question of manufacturing, sale and distribution of the misbranded cosmetics. There is no obligation to specify in the label date of packing and manufacturing of the article made or food or period within which the article has to be utilized. Learned counsel submits that the Government Analysis report also supports the case of the applicants as nothing contrary to the provisions of the Act of 1940 found in the drawn sample. On the other hand, it reveals from the report that, samples are of the standard quality and does not contain any hazardous or harmful substance for human use and are free from any chemical i.e. PPD and ammonia. Even Government Analysis has not declared said Mehendi product as misbranded. Learned counsel submits that, as per the provisions of Rule 138 of the Drugs and Cosmetics Rules, 1945 (hereinafter for the sake of brevity referred as Rules of 1945), application for grant or renewal of the licence to manufacture cosmetics for sale or for distribution shall be made up to ten items of each category of cosmetics categorized in Schedule M-II to the Licensing Authority appointed by the State Government in form No. 31 and it shall be accompanied by a prescribed licence fee. In view of the provisions of Rule 138 of Rules 1945, in the category of cosmetics as categorized in Schedule M-II, the product Mehendi is not mentioned. Chapter 15 of Rules of 1945 and most particularly, Rule 146 to 148 contends the provisions of manner of labelling and prohibition of sale or distribution. In rule 146 it has stated that, no person shall sell or distribute any cosmetic unless the cosmetic is manufactured by a licenced manufacturer and labelled and packed in accordance with these Rules.

Learned counsel submits that, if no licence is required for manufacturing the Mehendi, then the provisions of Rule 148 containing the manner of labelling does not apply to the Mehendi Product. Section 17-C particularly clause (b) says that a cosmetic shall be deemed to be misbranded, if it is not labelled in the prescribed manner. The learned counsel submits that, even accepting the allegations made in the complaint as it is, the charges levelled against the applicants in the complaint are not at all attracted. Learned counsel submits that, same is also evident from the circular dated 16.8.2010 issued by the Jt. Commissioner (Head Quarter), Controlling Authority, Food and Drugs Administration, wherein, it is stated that, so far as Mehendi Cone product is concerned, as per the provisions of the Drugs and Cosmetics Act and the Rules of 1945, the manufacturer thereof shall not be directed to obtain the licence, however, if any colour is used in the said Mehendi cone, they should be in conformity with the standard prescribed as per the annexure Q and further the PPD die should not be used in such a Mehendi Cone. It has stated in the said circular that such a manufacturer should be given understanding to that effect.

5. The learned A.P.P. submits that, during the raid in the premises of the applicants, it was found that the applicants were manufacturing and selling Mehendi Cone and Mehendi Powder and on the said product the batch number and manufacturing dates are not mentioned. It has mentioned on the Mehendi Cone that said product being manufactured at Nashik and thus it was the case of misleading information printed on the Mehendi Cone label. In response to the notice issued to the applicants, it has stated that said Prem Dulhan Mehendi Cone is being manufactured by him at Jalgaon by using raw materials like Mehendi Powder, Eucalyptus Oil, clove oil and water etc. Thus, the petitioner was manufacturing Mehendi Cone which was a cosmetic and there is a clear cut violation of section 17-C of the Act of 1940. The learned APP submits that, Prem Dulhan Mehendi Powder and Prem Dulhan Mehendi Cone is a cosmetic as per the provisions of Section 3 (aaa) of the Act of 1940 and Rules thereunder. The learned APP further submits that, so far as circular issued by the Jt. Commissioner (Head Quarter) and Controlling Authority, Food and Drugs Administration, Maharashtra State dated 16.8.2010 is concerned, this is a internal letter which cannot over ride the provisions of the Act. Further, the complaint is of the year 2006 where as the said circular is issued in the year 2010. The learned APP submits that the applicants violated the provisions of Section 18-C of the Act of 1940 by manufacturing the cosmetics by using chemicals and further carried out manufacturing activities without license and also misbranded the cosmetic articles.

6. The learned APP further submits that, as per the provisions of Rule 150-A of the Rules of 1945 and appended Schedule S, requirement of obtaining licence for cosmetic is made mandatory. As per the status of Heena Powder at Sr. No. 28 in Schedule S, it is clear that Mehendi Cone is nothing but a cosmetic product. The learned APP further admits that, said circular issued by the Jt. Commissioner (Head Quarter) and Controlling Authority, Food and Drugs Administration,

Maharashtra State dated 16.8.2010 is still in existence. In reply to the query of this Court, Additional Affidavit in reply was submitted by Shri Vijay S/o Tanaji Jadhav, Assistant Commissioner, Food and Drugs Administration, Jalgaon, wherein it is stated that, in view of the said circular issued by the Jt. Commissioner, Food and Drug Department, State of Maharashtra, dated 16.8.2010, the department of Food and Drugs Administration do not insist anybody to obtain license under the provisions of Drugs and Cosmetics Act, 1940 for manufacturing of Mehendi Cone.

7. On careful perusal of the complaint, it appears that, the charges levelled against the applicants in the complaint are mainly divided into two parts i.e. 1] - there is no valid license and 2]- said Mehendi Cone and Mehendi Powder was a misbranded cosmetic.

8. In view of the above, the provisions of Rule 138 of the Rules of 1945 are relevant. Rule 138 of the Rules 1945 reads as under :-

138. Application for licence to manufacture cosmetics [for sale or for distribution] :-

[(1) Application for grant or renewal of [licence to manufacture cosmetics for sale or for distribution] [shall be made up to ten items of each category of cosmetics categorized in schedule M-II to the Licensing Authority appointed by the State Government for the purpose of this part (hereinafter in this Part referred to as Licensing Authority) in Form 31 and shall be accompanied by a licence fee of rupees two thousand and five hundred and an inspection fee of rupees one thousand for every inspection thereof or for the purpose of renewal of licence.

(2) If a person applies for the renewal of licence after expiry but within six months of such expiry, the fee payable for the renewal of such licence shall be [rupees two thousand and five hundred plus an additional fee at the rate of rupees four hundred per month or part thereof in addition to an inspection fee of rupees one thousand].

(3) Application by a licensee to manufacture additional items of cosmetics shall be accompanied by a fee of rupees [one hundred for each item subject to a maximum of rupees three thousand for each application].

[(4) A fee of rupees [two hundred and] fifty shall be paid for duplicate copy of a licence issued under sub-rule (1), If the original is defaced, damaged or lost.]

9. Condition for grant or renewal of the licence in form No. 32 are laid down in Rule 139 of Rules of 1945. Rule 139 reads as under :-

139. Condition for the grant or renewal of a licence in Form 32. :-

Before a licence in Form 32 is granted or renewed, the following conditions shall be complied with by the applicant :

(1) The manufacture shall be conducted under the direction and personal supervision of a competent technical staff consisting of at least one person who is a whole-time employee and who possesses any one of the following qualification-

(a) hold a Diploma in Pharmacy approved by the Pharmacy Council of India under the Pharmacy Act, 1948 (8 of 1948), or

(b) is registered under the Pharmacy Act, 1948 (8 of 1948), or

(c) has passed the Intermediate Examination with Chemistry as one of the subjects or an examination recognised by the Licensing Authority as equivalent to it.

(d) (omitted).

[(2) The factory premises shall comply with the requirements and conditions specified in Schedule M-II.]

(3) (omitted)

(4) (omitted)

(5) The applicant shall either-

(i) provide and maintain adequate staff, premises and laboratory equipment for testing the cosmetic manufacture, and the raw materials used in the manufacture, or

(ii) make arrangements with some institution approved by the Licensing Authority [under Part XVI(A) of these Rules] for such tests to be regularly carried out in this behalf by the institution.

10. In Rule 138 of the Rules of 1945, the application for grant or renewal of licence to manufacture cosmetics for sale or for distribution shall be made up to ten items of each category of cosmetics categorized in Schedule MII to the Licensing Authority appointed by the State Government and as per the provisions of Rule 139 of the Rules 1945 the conditions as laid down in the Rules are required to be fulfilled before a licence is granted. Those conditions as laid down in Rule 139 of the Rules 1945 are mainly in respect of qualification of a competent technical staff and also certain requirements are to be fulfilled in the factory premises including laboratory equipment for testing the cosmetic manufacture, and the raw materials used in the manufacture etc. On careful perusal of the Schedule M-II I do not find the Mehendi Product categorized in Schedule M-II.

11. Further, in view of the Rule 142 of the Rules 1945, a licence shall be subject to the conditions stated therein and to the other conditions as mentioned in the Rules. Rule 142 reads as under :-

142. Conditions of licence. ?

A licence in form 32 shall be subject to the conditions stated therein and to the following other conditions, namely-

(a) The licensee shall provide and maintain staff, premises and equipment as specified in Rule 139.

(b) The licensee shall comply with the provisions of the Act and the rules made thereunder and with such further requirements, if any, as may be specified in any rules to be made hereafter under Chapter IV of the Act.

(b-1) The licensee shall keep records of the details of each batch of cosmetic manufactured by him and of raw materials used therein as per particulars specified in schedule U(1) and such records shall be retained for a period of three years.

(c) The licensee shall test each batch or lot of the raw materials used by him for the manufacture of the cosmetics and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests. The records or registers shall be retained for a period of three years from the date of manufacture.

(d) The licensee shall allow any [Inspector appointed under the Act] to enter with or without prior notice any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises and to take samples of the manufactured products under a receipt.

(e) The licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the rules made thereunder have been complied.

(f) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impression and the defects noticed:

[Provided that clauses (b-1) and (c) shall not apply to the manufacture of soap and the procedure for testing of raw materials and the records to be maintained by a manufacturer of soap shall be such as are approved by the Licensing Authority.]

12. Thus, the conjoint reading of Section 138, 139, 142 and Schedule M-II, it is clear that, no licence is required to manufacture Mehendi Cone or Mehendi Powder for sell or for distribution. The Jt. Commissioner, Head Quarters and Controlling Authority, has, thus issued the Circular to that effect in the year 2010 which still holds the field, wherein, it is stated unequivocally that no manufacturing licence is required for the manufacturing of Mehendi Products under the Provisions of Act of 1940. It is not the case that prior to issuance of the said circular, there were different provisions in the Act of 1940 and Rule of 1945 and in view of the certain amendments subsequently in the year 2010, the Jt. Commissioner constrained to issue the said circular dated 16.8.2010.

13. In Rule 150-A standard of Cosmetics is prescribed. As per Schedule S and in Schedule S item No. 28 is Heena Powder. It is stated in the Schedule S that, cosmetic as listed in the Schedule in finished form shall conform to the Indian Standards specifications laid down from time to time by the Bureau of Indian Standards (BIS). So far as entry no.28 Heena Powder is concerned, specifications as per the Indian Standard is mentioned as 11142.

14. In the Government Analysis report it has not mentioned that sample shall not conform to the Indian Standard Specifications. On the contrary, it has clearly mentioned in the report that, sample gives T.L.C. Identification test for the presence of Principal ingredients of genuine Heena Powder namely lawsone and chlorophyll 1 (reference is:11142:1984) Heena Powder. It has also stated in the report that, sample does not give identification test for the presence of ammonia, Para Phenyl Diamine (PPD), Turpentine Oil and Clove oil. It has only stated in the report that, N.B. details such as manufacturing licence number, batch number are not stated in the label.

15. Rule 146 and 148 specifically speaks about the labelling, packing and standard of Cosmetics. Rule 146 of the Rules of 1945 reads as under:-

146. Prohibition of sale or distribution - Subject to the other provisions of these rules, no person shall sell or distribute any cosmetic unless the cosmetic, if of Indian origin, is manufactured by a licensed manufacturer and labelled and packed in accordance with these rules.

16. Bare reading of Rule 146 makes it clear that, no person shall sell or distribute any cosmetic unless cosmetic, if of Indian Origin, is manufactured by a licensed manufacturer and labelled and packed in accordance with these Rules.

17. Thus, as discussed in the foregoing paragraphs by referring the provisions of Rule 138 of Rules 1945, if the Product Mehendi is not categorized in Schedule M-II, there is no question of obtaining any license for manufacturing the same for sell or for distribution. Consequently, for such a product there is no question of following the conditions of license as provided under Rule 142 of the Rules 1945 and the manner of labelling as prescribed under Rule 148 of the Rules of 1945.

18. In the light of the above discussion, continuation of the proceedings in RCC No. 487 of 2006 pending before the Chief Judicial Magistrate, Jalgaon would be gross abuse of the process of the Court. In the result, I proceed to pass the following order.

ORDER

I. Criminal Application is hereby allowed in terms of prayer clause "C".

II. Rule is made absolute in the above terms. Criminal Application is accordingly disposed of. sd/-