IN THE HIGH COURT OF JUDICATURE AT BOMBAY
BENCH AT AURANGABAD

CRIMINAL WRIT PETITION NO. 912 OF 2022

1. Kirti Kumar Jayantilal Patel
Age 59 years, Occ. Business,
R/o.7-8, Suraj Bungalow,
Opp. Pooj School, New Baroda Express,
Highway, C.T.M. Char Rasta Ahmedabad-26
Managing Director of M/s. Shree Umiya
Surgical Pvt. Ltd. Plot No.4704, GIDC,
Phase-IV, Ahmedabad-382445.

2. Smt. Umaben Kirti Kumar Patel,
Age.60 years, Occ. Business,
R/o. 7-8, Suraj Bungalow,
Opp. Pooj School, New Baroda Express,
Highway, C.T.M. Char Rasta Ahmedabad-26
Managing Director of M/s. Shree Umiya
Surgical Pvt. Ltd. Plot No.4704, GIDC,
Phase-IV, Ahmedabad-382445.

3. M/s. Shree Umiya Surgical Pvt. Ltd.
Plot No.4704, GIDC, Phase-IV,
Ahmednabad-382445.

.. Petitioners [original accused Nos. 2 to 4]

Versus

State of Maharashtra
At the instance of Drug Inspector,
Food and Drug Administration
M.S. Nanded.

.. Respondent

Mr.Shailendra S. Gangakhedkar, Advocate for the petitioners.
Mr.P.N. Kutti, APP for the respondent/State.

CORAM : KISHORE C. SANT, J.
RESERVED ON : 15.02.2023
PRONOUNCED ON : 31.03.2023

J U D G M E N T :-

01. Rule. Rule made returnable forthwith. The petition is taken up for final hearing at the stage of admission with consent of the parties.

02. This petition is filed by the Director and Managing Director of petitioner No. 3 – company having license to manufacture for sale (for distribution) of drugs specified in Schedule C, C(1) excluding those specified in Schedule-X under the license No.G/28/1329 issued by the Commissioner of Food and Drugs Control Administration, Gujarat State. The respondent is the State of Maharashtra through the Drug Inspector, Nanded, Food and Drug Administration, Maharashtra. A challenge in this petition is to an order of issuance of process dated 16.01.2006 passed by the learned Chief Judicial Magistrate, Nanded in a complaint in Special Case No.7 of 2015 (Old RCC No.12 of 2006).

03. The facts in short are that on 03.06.2005 the respondent drawn sample from drug store of Civil Hospital, Nanded of Mediplus Scalp vein set of size 20 having Batch No.26, manufactured on 01.10.2004 expiry date as 30.09.2007. Said sample was sent to analyst. The report dated 08.09.2005

from the analyst was received on 15.09.2005, wherein it was reported as "*The Sample Does Not Comply with I.P. requirements for tests for Sterility as given in the protocol.*" The complainant after getting the report, gave one copy of the test report with notice under section 18-A of the Drugs and Cosmetics Act, 1940 (for short " DC Act") to disclose the name of supplier by letter dated 15.09.2005. The complainant received letter dated 16.09.2005 from the Pharmacist, Drug Store, Civil Hospital, Nanded disclosing name of accused No.1, who happens to be a distributor. Sanction from the Controlling Authority & Joint Commissioner, Food & Drugs Administration, M.S. Mumbai dated 23.09.2005 was obtained by the complainant. The complainant sent copy of test report and one sealed counter part of the sample to petitioner No.1 – company, by communication dated 04.10.2005. On receiving necessary information from the accused-company and after completing all the formalities, lodged complaint on 04.01.2006. On 16.01.2006 the learned Chief Judicial Magistrate, Nanded passed following order :-

> "Read complaint and documents filed along with it.
> Issue process against accused for the offence punishable u/s 27(c) and 27(d) r/w sect. 34 of the Drugs & Cosmetics Act, 1940."

. The petitioners/original accused Nos.2 & 3 have thus appeared before this Court challenging the order of issuance of process. After receiving

the order from the Court for the first time, the petitioner got knowledge of the case in the month of April, 2022 from accused No.1 i.e. distributor and it is thereafter the petitioners approached this Court.

04. It is a specific case that till today no summons is served on the petitioners. The grounds on which the petitioners have approached this Court are mainly that the Mediplus Scalp vein set was manufactured on 01.10.2004 and was to expire in September, 2007. On the date of manufacture, the drug was complying with the standard or rather it was not included under section 3 (b) (iv) of the DC Act and there was no standard prescribed for the said item. The State of Maharashtra for the first time prescribed the standard in notification dated 06.10.2005. There cannot be retrospective effect given to the notification prescribing standard. By the time the notification was published, the drug was already in the market. Thus, while manufacturing, there was no violation of any of the provision of the Act. In this case, the drug is seized after more than one year from the date of manufacture.

05. The next ground taken is that the sample is not drawn from the Civil Surgeon, Nanded. Though it was seized on 03.06.2005, however, report

of the analyst received on 08.09.2005, i.e. after more than three months. From the sanction order it is seen that the Joint Commissioner (Head Office) and Controlling Authority, Food and Drug Administration, M.S., it is specifically stated that since the manufacturer is from out of the State, care be taken to comply with the provisions of sections 23 and 25 of the DC Act and only after making necessary inquiry and investigation, complaint be lodged. This consent was granted on 23.09.2005. Still no care is taken to comply with said sections 23 and 25. In the complaint also, the date of manufacturing is given as 01.10.2004. In the complaint, there is no averment that the standard that was prescribed for vein set was to apply with the retrospective effect. Thus, the learned Advocate for the petitioners submits that the impugned order does not show application of mind and submits that the order is passed in mechanical manner without considering the complaint and the material.

06. The learned APP at the outset raised objection as to maintainability of the petition. He submits that there was no question of complying with section 202 of the Cr.P.C., since the amendment requiring postponement of issue process is after order of issuance of process is passed. He further submits that though the drug is manufactured prior to notification

prescribing standard, however, it was being sold even after notification under section 3 and therefore that is clearly an offence. He submits that by order dated 04.10.2005, it was directed not to sell drug and to withdraw the sample from the market and the same is not done and therefore that is an offence. From the reply he pointed out that the petitioner did not reply the notice under section 18-B, by which it was requested to stop the sale as well as to withdraw the balance stock available in the market immediately, as the sample was not of standard quality. It was necessary to recall the product and therefore the petitioner is liable for an action.

07. The learned Advocate in rejoinder submitted that case is not made out in the complaint. He pointed out that in-fact the petitioners were given a license to produce the drugs till 31.12.2007 by the Food and Drug Control Administration, Gujarat State and thus in-fact he could have manufactured the said drug even after the date of notification by the State of Maharashtra.

08. The undisputed facts are that the alleged drug was manufactured on 01.10.2004. On that date no standard was prescribed. On 06.10.2005 a

notification came to be issued wherein for the first time a standard was prescribed by the Food and Drug Administration, Maharashtra State. The sample was collected on 03.06.2005. It was sent for analysis on 04.06.2005. The analyst prepared report on 08.09.2005. The complaint was filed on 04.01.2006 and order of issuance of process was passed on 16.01.2006.

09. On the submissions and dates noted above, following points arise for consideration :-

i. Whether the criminal writ petition is maintainable?

ii. Whether the order of issuance of process shows application of mind?

iii. Whether it was necessary to follow the procedure under section 202 of the Cr.P.C."

iv. In view of date of manufacturer, whether action can be taken on the basis of prescribing standard after the date of manufacture?

v. Whether there is violation of section 18 of the DC Act?

vi. What order?

10. On the point of maintainability, this Court finds that in view of judgment in the case of **Dhariwal Tobacco Products Ltd. & Ors. Vs. State of Maharashtra & Anr. reported in 2009 (2) SCC 370**, now it is well settled that

writ petition is maintainable. Application under section 482 of the Cr.P.C. is maintainable without challenging the order before the Revisional Court. The Hon'ble Apex Court also held in the case of **Pepsi Foods Ltd. Vs. Special Judicial Magistrate (1998) 5 SCC 749** that for the purpose of exercising of the powers vested in this Court under section 482 of the Cr.P.C. and under Article 227 of the Constitution of India so also of Revision are similar. This Court in view of above, holds that this writ petition can be directly entertained by this Court.

11. So far as application of mind while passing the order of issuance of process is concerned, this Court finds that it is clear that the learned Trial Judge has only passed order that he has read the complaint and documents filed along with it and issued process. There is no discussion or at-least mention of the reason as to what made the Court to come to a conclusion that prima facie case is made out to issue process against present petitioners. It is true that the Court need not give reasons in detail or make discussion in detail while issuing process. However, now it is well settled that the Court has to atleast prima facie observe that case is made out showing that the Court has applied its mind to the facts of the case and thereafter has come to the

conclusion that case is made out to issue process.

12. So far as inquiry as contemplated under section 202 of the Cr.P.C. is concerned, though the petitioners are residents of Gujarat State i.e. outside territorial jurisdiction of the learned Magistrate. The learned APP has rightly submitted that amendment mandatorily requiring inquiry under section 202 of the Cr.P.C. when the accused are staying beyond territorial jurisdiction of the Court came into force from 23.06.2006. In this case order of process is prior to the said date and therefore there is no violation of this provision. The learned Advocate for the petitioners has placed reliance on the judgment in the case of **Birla Corporation Limited Vs. Adventz Investments and Holdings Ltd. & Ors., (2019) 16 SCC 610**. In the said case, the Hon'ble Apex Court has considered and laid down the principles of exercise of inherent powers under section 482 of the Cr.P.C. The Hon'ble Apex Court has given one of the principles laid down – whether the Court has satisfied that criminal proceedings amount to abuse of process of Court is a ground to quash the proceedings. This Court finds that the learned Advocate for the petitioner has rightly relied upon the judgment in the case of **Birla Corporation (supra)**. Though this petition is filed under Article 227 of the Constitution of India,

however, the principles while quashing a complaint would be same and it has invoked section 482 of the Cr.P.C. Thus, both the points in respect of application of mind and section 202 of the Cr.P.C. are answered accordingly.

13. Next question that would fall for consideration is that in this case it is admitted fact that the drug was manufactured on 01.10.2004 having expiry period of three years. On the date of manufacture, there was no standard prescribed by Food and Drugs Administration, Maharashtra State. Vide notification dated 06.10.2005 the Ministry of Health and Family Welfare issued notification prescribing standard for the sterile devices intended for external or internal use in human beings as drugs with immediate effect, in which at Sr. No. (viii) present drug is mentioned. Thus, at least when the drug was manufactured, there was no standard prescribed by the State of Maharashtra for the said drug and certainly therefore manufacturer cannot be held responsible. This Court, therefore finds that prosecuting manufacturer would be clearly an abuse of process of law as a person cannot be held guilty for the act done prior to notification prescribing standard.

14. The complaint is filed for the offence under section 18(a)(i) of

the DC Act, which reads as under :-

> "18. **Prohibition of manufacturer and sale of certain drugs and cosmetics – From such date as may be fixed by the State** Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf-
>
> (a) **manufacture for sale or for distribution**, or sell, or stock or exhibit or offer for sale, or distribute-
>
> (i) **any drug** which is **not of a standard quality**, or is misbranded, adulterated or spurious;
>
> xxxxxxxxxx"

15. The bold words typed above from section 18(a)(i) of the Act would clearly show that no person shall manufacture drug which is not of standard quality from such date, which is fixed by the State Government by notification in the official gazette. In this case the gazette is dated 6th October, 2005 by which standard is prescribed for the first time and thus in no case it can be said that it has retrospective operation. Admittedly the drug is manufactured on 01.10.2004 and that fact is not disputed. Thus, no person shall be made to face prosecution for manufacturing a drug prior to prescribing certain standard. Hence, prosecuting the petitioner for manufacturing such drug would clearly be an abuse of process of law. Section 16 of the DC Act only prescribes standard. Section 27 of the DC Act which provides for penalty for manufacture, sale etc. of drug in contravention of Chapter IV of the Act.

16. Further going to the order granting consent, it is clearly seen that the Joint Commissioner (Head office) and Controlling Authority, Food and Drugs Administration clearly mentioned that since the petitioners are residents of different State, care be taken to comply section 23 and 25 of the Act. From the complaint, it is not seen that such care is taken before filing of the complaint. Though learned APP has raised point as to maintainability, which is already dealt, the judgment is cited by learned APP in the case of **Sanjay Kumar Rai Vs. State of U.P. reported in 2021 SCC OnLine SC 367**. He relied upon para 16 of the said judgment to show that the orders framing charges or refusing discharge are neither interlocutory nor final in nature and therefore are not affected by the bar under Section 397(2) of the Cr.P.C. It was held that High Court committed jurisdictional error by not entertaining the writ petition on merits and overlooking the fact that 'discharge' is a valuable right provided to the accused. With great respect, this Court finds that it was a case where the High Court had failed to exercise jurisdiction when revision petition was filed. However, it does not lay down that the writ petition or petition under section 482 is not maintainable. Next judgment cited by learned APP is of the Hon'ble Supreme Court in the case of **My Palace**

Mutually Aided Co-operative Society Vs. B. Mahesh & Ors. (Civil Appea No.5784 of 2022) to show that revision is maintainable. Reading both the judgments, this Court finds that Hon'ble Apex Court has not laid down that when remedy of revision is available, the writ petition is not maintainable.

17. Further submission of the learned APP that though sample report was received on 15.09.2005, however, there was delay is filing complaint and the same was for the reason that the Inspector had to gather information about the manufacture etc. However, it was countered by the learned Advocate for the petitioners rightly that on the date of seizure itself the Inspector was aware of the manufacturer etc. as all necessary details are mandatorily printed on the drug itself. Further, submission of the learned APP that prior to lodging the complaint notice was given under section 18-B by the Government to withdraw the drug from the market. However, for this charge, the petitioner cannot be made liable for such action as in 2004 itself the drug was sent to the distributor. It was for the distributor to act upon such a notice. The learned APP thereafter submits that the offence was continuing. He further submits that though notice was issued under section 18-B requesting to stop sale as well as withdraw balance stock available in the market, was

deliberately not replied by the petitioner. It is seen that section 18-B only prescribes to keep and maintain record and furnish to any officer or authority under the Act. It nowhere prescribes that the manufacturer has to withdraw the drug from market. From looking at the notice dated 04.10.2005 also nothing is seen as to that the petitioners were asked to withdraw the drug from the market. Thus, there is no substance in the submission of the learned APP.

18. This Court holds that the order of issuance of process was without application of mind. No case is made out showing that there was breach of any of the provisions of the Act by the present petitioners. It is clearly demonstrated that when the drug was manufactured, there was no standard prescribed for the said drug. The manufacturer cannot be faulted with for not manufacturing the drug for which the standard is prescribed after the date of manufacture. The action initiated by the respondent itself is thus against the law. A person is expected to abide the law as it exists on the date of alleged act. The respondent has not come up with a case that on the date of manufacture the standard was prescribed. The only case of the respondent is that even after prescribing of the standard, the drug that was already

circulated in the market was not withdrawn from the market. The petitioner is right in submitting that after manufacturing of the drug, it went through a chain of distributor, whole-seller, retailer etc. The respondent has not come up with a case that the petitioner had any control over the drugs after it was circulated in the market.

19. This Court after considering the submissions and in view of the judgments cited by the parties is of the view that case is clearly made out calling for interference under Article 227 of the Constitution of India. Under such circumstances, if the prosecution is allowed to proceed, it would certainly an abuse of process of law. Hence, the writ petition is allowed in terms of prayer clause (B).

20. Rule made absolute accordingly.

[KISHORE C. SANT, J.]

snk/2023/MAR23/crwp912.22