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S. ATHILAKSHMI

v.

THE STATE REP. BY THE DRUGS INSPECTOR

(Criminal Appeal No. 804 of 2023)

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MARCH 15, 2023

[KRISHNA MURARI AND SUDHANSU DHULIA, JJ.]

- Drugs and Cosmetics Act, 1940 – ss.18(c), 27(b)(ii) – Prosecution of appellant u/s.18(c) punishable u/s.27(b)(ii) – Held: C Prohibition u/s.18(c) is on the manufacturing, distribution, stocking or exhibition of medicines for the purposes of sale – In the present case, prosecution against the appellant was unwarranted – Appellant is a registered medical practitioner along with the fact that the quantity of medicines seized was extremely small, a quantity which can be easily found in the house or a consultation room of a D doctor – Considering the small quantity of medicines, most of which are in the category of lotions and ointments, it cannot be said that such medicines could be ‘stocked’ for sale and would come in the category of stocking of medicines for the purpose of sale – No offence is made out – It is not the case of the prosecution that the E Appellant was selling drugs from an open shop across the counter – It is possible that she was distributing these drugs to her patients for emergency uses and thus she is protected by the Act itself – An exception has been created under Schedule ‘K’ r/w r.123 in favour of medical practitioner; the appellant ought to have been given the benefit of these provisions – Further, the sanction for prosecution F given in the instant case, prima facie, suffers from the vice of non-application of mind – Order of the High Court set aside – Criminal proceedings against appellant quashed – Drugs and Cosmetics Rules, 1945 – Schedule K – Drugs and Cosmetics Rules, 1940 – r.123 – Code of Criminal Procedure, 1973 – s.482.*

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Allowing the appeal, the Court

- HELD:** 1.1 It is not the case of the prosecution that the Appellant was selling drugs from an open shop across the counter. She is a senior doctor who is engaged as an Associate Professor and Head of Department, Dermatology in a Government Medical H College, and being a medical practitioner, under certain conditions,

she is also protected under the law which has been referred to above. Considering the small quantity of medicines, most of which are in the category of lotions and ointments, it cannot be said by any stretch of imagination that such medicines could be ‘stocked’ for sale and would come in the category of stocking of medicines for the purpose of sale. When small quantity of medicine has been found in the premises of a registered medical practitioner, it would not amount to selling their medicines across the counter in an open shop. In fact, this is not even the allegation against the Appellant. Undoubtedly, the provisions of Section 18 and are relevant provisions under the law, which have a social purpose, which is to protect ordinary citizens from being exploited *inter alia*, by unethical medical practitioners, and for this reason the punishment under Section 27 can extend up to 5 years under the law, and has a minimum punishment of 3 years. But given the facts and circumstances of the case and considering that the Appellant is a registered medical practitioner, along with the fact that the quantity of medicines which have been seized is extremely small, a quantity which can be easily found in the house or a consultation room of a doctor, no offence is made out in the present case. In fact, an exception has been created under Schedule ‘K’ read with Rule 123 to the rules, the appellant ought to have been given the benefit of these provisions and such a registered medical practitioner should not have been allowed to face a trial where in all likelihood the prosecution would have failed to prove its case beyond reasonable doubt. [Paras 8, 9][922-A-F]

1.2 What the High Court failed to consider, however, is the provisions contained in Rule 123 read with Schedule ‘K’ to the 1945 Rules and when admittedly it is not the case of the prosecution that the drugs which were seized were being sold in an open shop across the counter. Since this was not being done, and an exception is created under the law in favour of the medical practitioner where the drugs given in Schedule ‘K’ would be exempted from the purview of Chapter 4 of the Act, prosecution against the Appellant is unwarranted. The sanction for prosecution given in the present case appears, *prima facie*, to suffer from the vice of non-application of mind. There is no reference to any of the documents, evidence or the submissions

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- A submitted by either of the parties, no reasons assigned or even an explanation pertaining to the delay which indicates it has been passed in a mechanical manner. [Paras 10, 14][923-D, 924-F]

Hasmukhlal D. Vohra and Anr. v. State of Tamil Nadu
2022 SCC OnLine SC 1732; Mansukhlal Vithaldas

- B *Chauhan v. State of Gujarat (1997) 7 SCC 622 : [1997] 3 Suppl. SCR 705; Mohd. Shabir v. State of Maharashtra (1979) 1 SCC 568 : [1979] 2 SCR 997 – relied on.*

Case Law Reference

- C [1997] 3 Suppl. SCR 705 relied on Para 14
 [1979] 2 SCR 997 relied on Para 15

CRIMINAL APPELLATE JURISDICTION: Criminal Appeal No. 804 of 2023.

- D From the Judgment and Order dated 21.06.2022 of the High Court of Judicature at Madras in CRLOP No. 5579 of 2020.

S. Nagamuthu, Sr. Adv., M.P. Parthiban, Ms. Priya Ranjini Nagamuthu, A.S. Vairawan, R. Sudhakaran, Vikash Rajkumar, Subrahmanya Bhanu, Devendran, Alagendiran, Advs. for the Appellant.

- E V. Krishnamurthy, A.A.G., Dr. Joseph Aristotle S., Shobhit Dwivedi, Ms. Richa Vishwakarma, Advs. for the Respondent.

The Judgment of the Court was delivered by

SUDHANSU DHULIA, J.

- F Leave granted.

2. The Appellant before this Court is a registered medical practitioner who is presently working as an Associate Professor and the Head of Dermatology Department, in the Government Omandurar Medical College, Chennai. In the past, she has held the post of Assistant

- G Professor and Civil Surgeon at Royapettah Medical College. It is permissible for her under the law to practice medicine when she is not performing her official duties. The Appellant, in her individual and independent capacity was carrying on her medical practice at a premises which is No. 87, Red Hills Road (North), Villivakkam, at Chennai. It is

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here that she could be consulted and where she meets and examines her patients. A

3. An inspection was made on the above premises by the Drugs Inspector, Villivakkam Range on 16.03.2016. As per inspection report, the Drugs Inspector found the following medicines in the inner room of her premises. B

S No.	Name of Drug	Quantity	M.R.P (Rs.)
1.	Denidol Lotion 50ml	1 No.	198.50
2.	Salico Lotion 30ml	4 Nos.	75/30 ml.
3.	A-CN Gel 20 gms	1 No.	98/20gms
4.	Tebir Gel 10 gms	9 Nos.	47.90/10gms
5.	Soltop-S.6% Lotion (30ml)	4 Nos.	125/30ml
6.	Mycotin Cream 15 gms	3 Nos.	115/15gms
7.	Mopry 2% Ointment	4 Nos.	75.60/5gms
8.	Momtop-S Ointment (10gms)	1 No.	145/10gms
9.	ESM Cream (10gms)	4 Nos.	76/10gms
10.	Nu-Whitified Ointment (20gms)	7 Nos.	40/20gms
11.	Momesone Cream (15gms)	3 Nos.	82/15gms
12.	Sudif Cream (10gms)	4 Nos.	99/10gms
13.	CAP Gel (15gms)	1 No.	156/15gms
14.	Kenozole Cream (30gms)	2 Nos.	130/30gms
15.	Soltop-S 3% Ointment	1 No.	125/30gms
16.	Zylo AC gel 2.5% (20gms)	1 No.	99.74/30gms
17.	Ketzi cream (30gms)	1 No.	99.47/30gms
18.	Ketoff lotion (60ml)	2 Nos.	150/60ml

The Drugs Inspector also referred to certain sale bills of medicines which are as follows: F

Sr. No.	Bill No. & Date	Name of the Drug	Qty. Sold
1	409 dated 24/02/2016	Mycotin Cream Nufoce Power Certrezol – L tablets	1 No. 1 No. 10 Tablets
2	423 dated 9/03/2016	Certivera Lotion ESM Cream ILor or Tablets Cetrezol L Tablets	1 No. 1 No. 10 Tablets 10 Tablets
3	426 dated 11/03/2016	Adixied Tablets CAP Gel AFK Lotion CAN Soap Zit care Tablets	2 Strips 1 No. 1 No. 1 No. 2 strips
4	424 dated 9/03/2016	P Scab Lotion 1 for Tablets Loxip Tablets	1 No. 10 Tablets 10 Tablets
5	428 dated 11/03/2016	Cultivera Location Momesone Cream Cetrezol – L tablets	1 No. 1 No. 10 Tablets

- A 4. The Drugs Inspector thereafter moved an application for obtaining sanction from the office of the Director of Drugs Control, Tamil Nadu, Chennai-06 on 22.09.2016 which was given to him on 23.01.2018. Consequently, the Drugs Inspector filed a complaint before the Court of X Metropolitan Magistrate, Egmore, for prosecuting the Appellant under Section 18(c) of the Drugs and Cosmetics Act, 1940 punishable under Section 27(b)(ii) of the Act.
- B 5. Aggrieved by these proceedings, the Appellant filed an application under Section 482 of the Code of Criminal Procedure, 1973 before the High Court of Madras for quashing the criminal proceedings.
- C Her petition was dismissed by the Ld. Single Judge on 21.06.2022. Aggrieved by this, the Appellant has filed Special Leave Petition before this Court against the order of the Single Judge.
- D 6. Under Section 18 of Drugs and Cosmetics Act 1940, a prohibition has been imposed as to the manufacture, sale etc. of certain drugs and cosmetics. Section 18 reads as follows:
- 18. Prohibition of manufacture 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—
- E (a)
- F (b) [sell or stock or exhibit or offer for sale,] or distribute any drug [or cosmetic] which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;
- G (c) [manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale,] or distribute any drug [or cosmetic], except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter:
- H Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:
- I Provided further that the [Central Government] may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the

notification, the [manufacture for sale or for distribution, sale, stocking or exhibiting or offering for sale] or distribution of any drug or class of drugs not being of standard quality. A

The punishment for contravention of Section 18(c) is provided under Section 27(b)(ii) which reads as follows:

27. Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter— Whoever, himself or by any other person on his behalf, manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes— B

(a) xxxxxxxxxxxxxxxxxxxxxxxxx C

(b) any drug –

(i) xxxxxxxxxxxxxxxxxxxxxxxxx

(ii) without a valid licence as required under clause (c) of section 18, shall be punishable with imprisonment for a term which shall [not be less than three years but which may extend to five years and with fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more]: D

Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of [less than three years and of fine of less than one lakh rupees]; E

7. As we can see the prohibition under Section 18(c) is on the manufacturing, distribution, stocking or exhibition of medicines for the purposes of sale. The charge in the present case is that the Appellant had “stocked” medicines for “sale”. The entire emphasis is on “sale” of these medicines. This is evident from the sanction being sought by the Drug Inspector from the office of the Director, Drugs Control, Tamil Nadu wherein as per the sanction letter dated 23.01.2018, he had said that the Appellant be prosecuted for the contravention of: F

“Section 18(c) of Drugs and Cosmetics Act 1940 for having stocked drugs for sale and sold the drugs without having a valid drug license, which is punishable under section 27(b)(ii) of the said Act”. G

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- A Thus, as per the prosecution she had stocked the drugs and sold them. What the Director of Drugs Control and the High Court lost sight of is the fact that the Appellant is a registered medical practitioner, her area of specialization being dermatology. She has an M.D. (DVL) degree in this specialisation. It is not a case that she had opened a shop in her premises from where she was selling drugs and cosmetics across the counter! It is possible that she was distributing these drugs to her patients for emergency uses and thus she is protected by the Act itself. Schedule (K) which is a part of the Drugs and Cosmetics Rules, 1945 provides an exemption which we shall examine hereafter.
- C 8. Under Section 33 of the Act, the Central Government can make rules which have to be laid before the Parliament for its ratification under Section 38 of the Act. These rules have been framed which is known as Drugs and Cosmetics Rules, 1940. Rule 123 of the rules exempts certain drugs from the provisions of Chapter IV of the Act (which includes both Section 18 and Section 27 referred above, which are penal provisions), under certain conditions Rule 123 reads as under:

“123. The drugs specified in Schedule K shall be exempted from the provisions of Chapter IV of the Act and the rules made thereunder to the extent and subject to the conditions specified in that Schedule.”

- E Entry No. 5 under Schedule (K) are the drugs which are supplied by a registered medical practitioner with which we are presently concerned. The relevant provision of Schedule (K) reads as under:-

Schedule K

F (See Rule 123)

	Class of Drugs	Extent and Conditions of Exemptions
G	1. XXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXX
	2. XXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXX
	3. XXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXX
	4. XXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXX

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<p>5. Drugs supplied by a registered medical practitioner to his own patient or any drug specified in Schedule C supplied by a registered medical practitioner at the request of another such practitioner if it is specially prepared with reference to the condition and for the use of an individual patient <u>provided the registered medical practitioner is not (a) keeping an open shop or (b) selling across the counter or (c) engaged in the importation, manufacture, distribution or sale of drugs in India to a degree which render him liable to the provisions of Chapter IV of the Act and the rules thereunder.</u></p>	<p>All the provisions of Chapter IV of the Act and the Rules made thereunder, subject to the following conditions:</p> <p>[1. The drugs shall be purchased only from a dealer or a manufacturer licensed under these rules, and records of such purchases showing the names and quantities of such drugs, together with their batch numbers and names and addresses of the manufacturers shall be maintained. Such records shall be open to inspection by an Inspector appointed under the Act, who may, if necessary, make enquiries about purchases of the drugs and may also take samples for test.]</p> <p>2. In the case of medicine containing a substance specified in [Schedule G, H or X] of the following additional conditions shall be complied with:-</p> <ul style="list-style-type: none"> a. the medicine shall be labelled with the name and address of the registered medical practitioner by whom it is supplied; b. if the medicine is for external application, it shall be labelled with the words [***] — “For external use only” or, if it is for internal use with the dose; c. the name of the medicine or ingredients of the preparation and the quantities thereof, the dose prescribed, the name of the patient & the date of supply and the name of the person who gave the prescription shall be entered at the time of supply in register to be maintained for the purpose; d. the entry in the register shall be given a number and that number shall be entered on the label of the container; e. the register and the prescription, if any, on which the medicines are issued shall be preserved for not less than two years from the date of the last entry in the register or the date of the prescription, as the case may be. <p>3. The drug will be stored under proper storage conditions as directed on the label.]</p> <p>4. No drug shall be supplied or dispensed after the date of expiration of potency recorded on its container, label or wrapper or in violation of any statement or direction recorded on such container, label or wrapper.]</p>
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(emphasis supplied)

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- A It is not the case of the prosecution that the Appellant was selling drugs from an open shop across the counter. She is a senior doctor who is engaged as an Associate Professor and Head of Department, Dermatology in a Government Medical College, and being a medical practitioner, under certain conditions, she is also protected under the law which has been referred to above.
- B 9. Considering the small quantity of medicines, most of which are in the category of lotions and ointments, it cannot be said by any stretch of imagination that such medicines could be ‘stocked’ for sale and would come in the category of stocking of medicines for the purpose of sale.
- C When small quantity of medicine has been found in the premises of a registered medical practitioner, it would not amount to selling their medicines across the counter in an open shop. In fact, this is not even the allegation against the Appellant. Undoubtedly, the provisions of Section 18 and 27 are relevant provisions under the law, which have a social purpose, which is to protect ordinary citizens from being exploited *inter alia*, by unethical medical practitioners, and for this reason the punishment under Section 27 can extend up to 5 years under the law, and has a minimum punishment of 3 years. But given the facts and circumstances of the case and considering that the Appellant is a registered medical practitioner, along with the fact that the quantity of medicines which have been seized is extremely small, a quantity which can be easily found in the house or a consultation room of a doctor, in our considered view no offence is made out in the present case. In fact, an exception has been created under Schedule ‘K’ read with Rule 123 to the rules, the appellant ought to have been given the benefit of these provisions and such a registered medical practitioner should not have been allowed
- F to face a trial where in all likelihood the prosecution would have failed to prove its case beyond reasonable doubt. The learned single judge while dismissing the application under Section 482 Cr.P.C of the appellant has relied upon a decision of this Court:
- G “9. It is too late in the day to seek reference to any authority for the proposition that while invoking the power under Section 482 Cr.P.C. for quashing a complaint or a charge, the Court should not embark upon an enquiry into the validity of the evidence available. All that the Court should see is as to whether there are allegations in the complaint which form the basis for the ingredients that constitute certain offences complained of The Court may
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also be entitled to see {i) whether the preconditions requisite for taking cognizance have been complied with or not; and {ii) whether the allegations contained in the complaint, even if accepted in entirety, would not constitute the offence alleged

.....

13. A look at the complaint filed by the appellant would show that the appellant had incorporated the ingredients necessary for prosecuting the respondents for the offences alleged. The question whether the appellant will be able to prove the allegations in a manner known to law would arise only at a later stage
.....”

10. But what the High Court failed to consider, however, is the provisions contained in Rule 123 read with Schedule ‘K’ to the 1945 Rules and when admittedly it is not the case of the prosecution that the drugs which were seized were being sold in an open shop across the counter. Since this was not being done as visualized above, and an exception is created under the law in favour of the medical practitioner where the drugs given in Schedule ‘K’ would be exempted from the purview of Chapter 4 of the Act, we are of the considered view that prosecution against the Appellant is unwarranted.

11. The backbone of the Respondent’s case is the sales bills with the list of 18 drugs seized from the premises of the Appellant. However, the details of the sales bills and seized drugs in the Show Cause Notice issued by the Respondent it is seen that the sales bills are not even for the medicines which have been seized by the Respondent.

12. On the contrary, upon being served with the Show Cause Notice, the Appellant was directed, under Section 18-A, to reveal the name and addresses of persons from whom she obtained the drugs which were seized. In compliance with the same, Appellant has produced multiple invoices from pharmaceutical shops to show her *bonafides*. Further, upon inspection of the drugs by the Drugs Testing Laboratory, Tamil Nadu they returned a finding that the drugs were of ‘standard quality’ which indicates it is not a case where the Appellant was operating a shop to sell spurious medicines over the counter.

13. Another factor which must be considered is that the search was carried out on 16.03.2016 and sanction for prosecution was sought

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- A on 22.09.2016 and the sanction ultimately was given on 23.01.2018. There is no explanation which has been given for this delay in getting the approval. In the recently decided case of *Hasmukhlal D. Vohra and Anr. v. State of Tamil Nadu*¹, criminal proceedings were quashed against a Petitioner on the grounds that the substance in question was not a drug under Indian Pharmacopoeia. One of the considerations was the delay in the proceedings against which the following observations were made,
- B *'25. In the present case, the Respondent has provided no explanation for the extraordinary delay of more than four years between the initial site inspection, the show cause notice, and the complaint. In fact, the absence of such an explanation only prompts the Court to infer some sinister motive behind initiating the criminal proceedings.'*
- C *'26. While inordinate delay in itself may not be ground for quashing of a criminal complaint, in such cases, unexplained inordinate delay of such length must be taken into consideration as a very crucial factor as grounds for quashing a criminal complaint.'*
- D *'27. While this court does not expect a full-blown investigation at the stage of a criminal complaint, however, in such cases where the accused has been subjected to the anxiety of a potential initiation of criminal proceedings for such a length of time, it is only reasonable for the court to expect bare-minimum evidence from the Investigating Authorities.'*
- E 14. The sanction for prosecution given in the present case appears, *prima facie*, to suffer from the vice of non-application of mind. There is no reference to any of the documents, evidence or the submissions submitted by either of the parties, no reasons assigned or even an explanation pertaining to the delay which indicates it has been passed in a mechanical manner. This Court in the case of *Mansukhlal Vithaldas Chauhan v. State of Gujarat*², highlighted the importance of a prior sanction granted under Section 197 of the Code of Criminal Procedure, 1973 while quashing the criminal proceedings instituted against a Divisional Accountant engaged with the Medium Irrigation Project Division, Gujarat. It was observed as follows:
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¹ 2022 SCC OnLine SC 1732

² (1997) 7 SCC 622

‘19. Since the validity of “sanction” depends on the applicability A
of mind by the sanctioning authority to the facts of the case as
also the material and evidence collected during investigation, it
necessarily follows that the sanctioning authority has to apply its
own independent mind for the generation of genuine satisfaction
whether prosecution has to be sanctioned or not.’

15. The possession of the drugs is not disputed in this case by either side. However, this Court in the case of *Mohd. Shabir v. State of Maharashtra*³ while allowing an appeal in part and directing the release of an Appellant who had been prosecuted under the provision 18(c) of the 1940 Act, this Court observed that possession simpliciter would not itself be an offence but the prosecution had to prove the essential ingredient under Section 27 which was that even a ‘stock’ of the medicine was for sale. It was observed as follows:

‘4. ...We, therefore, hold that before a person can be liable D
for prosecution or conviction under Section 27(a)(i)(ii) read
with Section 18(c) of the Act, it must be proved by the
prosecution affirmatively that he was manufacturing the drugs
for sale or was selling the same or had stocked them or
exhibited the articles for sale. The possession simpliciter of
the articles does not appear to be punishable under any of
the provisions of the Act. If, therefore, the essential ingredients
of Section 27 are not satisfied the plea of guilty cannot lead
the Court to convict the appellant.’

16. The sanctioning authority had not examined at all whether a practising doctor could be prosecuted under the facts of the case, considering the small quantity of the drugs and the exception created in favour of medical practitioner under Rule 123, read with the Schedule “K”. All these factors ought to have been considered by the sanctioning authority. Under these circumstances we allow this appeal and set aside the order of the learned Single Judge of the Madras High Court and quash the criminal proceedings in Criminal Case No. 7315 of 2018 on the file of X Metropolitan Magistrate, Egmore, Chennai.

Divya Pandey
(Assisted by : Adiraj Bali and Shevali Monga, LCRAs)

Appeal allowed.