

Rajinder Gupta Vs. the State

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Court : Delhi

Decided On : Aug-22-2005

Reported in : 2006CriLJ674; 123(2005)DLT55; 2005(84)DRJ477

Judge : Badar Durrez Ahmed, J.

Acts : [Narcotic Drugs and Psychotropic Substances Act 1985](#) - Sections 8, 21, 22, 29 and 64 to 67; Narcotic Drugs and Psychotropic Substances Rules, 1985; [Drugs and Cosmetics Act, 1940](#); Drugs and Cosmetics Rules, 1945 - Rules 65, 65(1), 97(1) and 104

Appeal No. : Bail Application 73/2005

Appellant : Rajinder Gupta

Respondent : The State

Advocate for Def. : Satish Aggarwal, ; Ashish Aggarwal, ; Mala Sharma, ;

Advocate for Pet/Ap. : K.K. Sud and; K.T. S. Tulsi, Sr. Advs.,; Jayant K. Sud,

Judgement :

Badar Durrez Ahmed, J.

A1. The common questions in these bail applications are:

1) Whether Buprenorphine Hydrochloride is a 'psychotropic substance' within the meaning of the Narcotic Drugs and Psychotropic Substances Act, 1985 (hereinafter referred to as the NDPS Act) ?

2) If yes, whether Buprenorphine Hydrochloride is a 'psychotropic substance' to which Chapter VII of the Narcotic Drugs and Psychotropic Substances Rules, 1985 (hereinafter referred to as the NDPS Rules) apply To what effect ?

It was contended by the petitioners that Buprenorphine Hydrochloride I.P. Injections which are the subject matter of the present applications are drugs specified under the [Drugs and Cosmetics Act, 1940](#) and conform to standards indicated in the Indian Pharmacopoeia. According to the learned counsel for the petitioners, since the Buprenorphine Hydrochloride injections involved in the present applications conformed to the specifications mentioned in the Indian Pharmacopoeia and were Schedule 'H' Drugs under the [Drugs and Cosmetics Act, 1940](#) and the Drugs and Cosmetics Rules, 1945, the same could not be regarded as 'psychotropic substances' at all under the NDPS Act. On the other hand, learned counsel who appeared for the Respondents, urged that Buprenorphine Hydrochloride was a psychotropic substance within the meaning of the NDPS Act and that it made little difference if it also happened to be a Schedule 'H' Drug.

A2. In the first instance, it is to be determined as to whether Buprenorphine Hydrochloride I.P. injections are covered under the definition of psychotropic substances under the NDPS Act. If they are not to be regarded as psychotropic substances then, clearly, no offence under the NDPS Act would be made out and the petitioners would straight away be entitled to be enlarged on bail. On the other hand, if it were to be held that the same were psychotropic substances then Question No. 2 would require an answer. It would have to be seen as to whether merely because Buprenorphine Hydrochloride was a psychotropic substance this in itself would entail that its manufacture, sale, possession, transport, etc., would trigger the punishments under the NDPS Act, particularly the punishment under Section 22 thereof.

Re: Question No.1:

A3. Let me examine the provisions with regard to Buprenorphine Hydrochloride in the [Drugs and Cosmetics Act, 1940](#) (hereinafter referred to as the 'D and C Act'), the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the 'D and C Rules'), the NDPS Act and the NDPS Rules. Rule 65 of the D and C Rules prescribes the general conditions for licenses in Forms 20, 20A, 20B, 20F, 20G, 21 and 21B. For example sub-rule (3)(1) of Rule 65 stipulates that the supply of any drug, other than those specified in Schedule X, on the prescription of a Registered Medical Practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose and the Serial number of entry in the register shall be entered on the prescription. Several particulars are required to be entered in the Register such as, Serial number of the entry, the date of supply, the name and address of the prescriber etc. In the case of a drug specified in Schedule `H', it is also necessary to record the name of the manufacturer of the drug, its batch number and the date of expiry of potency, if any.

Rule 97 of the D and C Rules contains stipulations with regard to the labelling of medicines. It specifically provides that the container of a medicine for internal use shall, if it contains a substance specified in Schedule `H', be labeled with the symbol Rx conspicuously displayed on the top left corner of the label and shall also be labelled with the following words:-

'Schedule `H' drug Warning: to be sold by retail on the prescription of a Registered Medical Practitioner only.'

This is so provided in Rule 97(1)(b) of the D and C Rules. However, if the substance contained in the container is one specified in Schedule `H' and also comes within the purview of the NDPS Act, it is required to be labelled with the symbol NRx , which shall be in red and conspicuously displayed on the left top corner of the label, and be also labelled with the following words:-

'Schedule H drug G' Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only'.

This is so provided in Rule 97(1)(c) of the D and C Rules. I may also mention Rule 104 of the said Rules which provides that the letters 'IP' and recognised abbreviations of the pharmacopoeias and official compendia of drug standards prescribed under these rules shall be entered on the label of the drug only for the purpose of indicating that the drug is in accordance with standards set out in the Indian Pharmacopoeia or in any such pharmacopoeia or official compendium of drug standards recognised under the Rules. An examination of Schedule 'H' of the D and C Rules makes it clear that Buprenorphine Hydrochloride is listed therein as a 'Prescription Drug.'

A4. From an analysis of the above provisions, it is clear that Buprenorphine Hydrochloride, if it conforms to the standards prescribed under the Indian Pharmacopoeia, is to be known as Buprenorphine Hydrochloride I.P. It is further clear that Buprenorphine Hydrochloride is a prescription drug specified in Schedule 'H' and is to be sold by retail only on the prescription of a Registered Medical Practitioner. The stipulation with regard to the entries made in the Register as prescribed under Rule 65 have also to be complied with by the retailer making the sales. It is also to be noted that a reading of Rule 97(1)(c) clearly indicates that it is quite possible that a drug falling within the meaning of the [Drugs and Cosmetics Act, 1940](#) and the D and C Rules and particularly one falling under Schedule 'H' can also fall within the purview of the NDPS Act. If it is so, the manufacturer is duty bound to place the symbol NRx in red on the top left corner of the label.

A5. I now come to the provisions under the NDPS Act. Section 2(ixia) defines 'psychotropic substances' as under:-

'(ixia) 'psychotropic substance' means any substance, natural or synthetic or any natural material or any salt or preparation of such substance or materials included in the list of psychotropic substances specified in the Schedule.'

A plain reading of the above definition makes it clear that a psychotropic substance could be any substance, natural or synthetic, or any natural material or 'any salt or preparation' of such substance or materials included in the list of psychotropic substances specified in the Schedule. For this purpose, a reference

to the Schedule becomes necessary. The Schedule to the NDPS Act gives a list of psychotropic substances. Entry Nos. 92 and 110 are relevant and they read as under:-

SL.No	INTERNATIONAL NON-PROPRIETARY NAMES	CHEMICAL NAME	OTHER NON-PROPRIETARY NAMES
92	BUPRENORPHINE	21-cyclopropyl-7-[(S)-1 hydroxy-1,2,2-trimethyl propyl]-6, 14-endo, ethano-6, 7, 814-tetrahydrooripavine.	
110	Salts and Preparations of above		

Entry No. 110 was originally entry No 77. It was re-numbered as Entry No. 106 in 1992 and as Entry No. 110 with effect from 11th June, 2003. From a conjoint reading of Section 2(ixia) and the aforesaid Entry Nos 92 and 110 of the Schedule to the NDPS Act, it becomes clear that Buprenorphine Hydrochloride is not mentioned by name in the Schedule and that it is only Buprenorphine which has been listed as a psychotropic substance. The next question to be answered is whether Buprenorphine Hydrochlorides a 'salt or preparation' of Buprenorphine which is a psychotropic substance specified in the Schedule to the NDPS Act. The word 'preparation' is defined under the NDPS Act in Section 2(ax) thereof as under:-

'2(ax) 'Preparation' in relation to a narcotic drug or psychotropic substance, means any one or more such drugs or substances in dosage form or any solution or mixture, in whatever physical state, containing one or more such drugs or substances:

If Buprenorphine Hydrochloride were to be a preparation of Buprenorphine, in terms of the aforesaid definition, it would have to be in dosage form or any solution or mixture, in whatever physical state, containing Buprenorphine. Buprenorphine Hydrochloride, as admitted by all the counsel appearing in the matter, is neither a solution nor a mixture of Buprenorphine. In fact, it is an entirely different compound. Furthermore, it could also not be regarded as Buprenorphine in dosage form. thereforee, it is clear that Buprenorphine Hydrochloride cannot be regarded as a 'preparation' of Buprenorphine. Consequently, I am left with the only alternative consideration and that is--whether Buprenorphine Hydrochloride is a 'salt' of Buprenophine? If it is, then it would be a psychotropic substance within the

meaning of Section 2(xxiii) as well as Entry 110 read with Entry 92 of the Schedule to the NDPS Act. For this purpose I had, during the course of hearing, sought clarifications from the Chemical Examiner with regard to the nature of Buprenorphine Hydrochloride. The letter dated 8th January, 2005 written by the Chemical Examiner Grade-II, Customs Laboratories, Customs House, Kandla, addressed to Mr Satish Aggarwal, Senior Special Public Prosecutor was placed before me. In that letter, it has been stated that Buprenorphine Hydrochloride is a salt of Buprenorphine. It was further indicated that Buprenorphine and its salts including Buprenorphine Hydrochloride give a positive test for Buprenorphine on testing. A similar letter by the same Chemical Examiner was written on 3rd of February, 2005 where he has again indicated as under:-'In my opinion Buprenorphine Hydrochloride may be said to be a salt of Buprenorphine'.

A6. Thereafter, the Joint Director (Dr. Y.K.S. Rathore), Central Revenue Control Laboratory, Hill Side Road, Pusa, New Delhi by his letter dated 4th February, 2005 also confirmed that Buprenorphine Hydrochloride is a salt of Buprenorphine. Furthermore, four specific queries were raised by me during the course of arguments and they were as under:-

- '1. Why is Buprenorphine dissolved in Hydrochloric Acid?
2. Why does Buprenorphine dissolve in Hydrochloric Acid and why not in water?
3. Whether the combination of Buprenorphine and Hydrochloric acid is a compound or a mixture? And
4. Can Buprenorphine hydrochloride be called a solution of Buprenorphine salt?

In response to this, a letter dated 22nd February, 2005 by the Chemical Examiner, Central Revenue Control Laboratory, was placed before me. The answers were as under:-

'The point wise reply to above referred letter is as under:-

- i) Why Buprenorphine is dissolved in Hydrochloride acid? (ii) Why Buprenorphine dissolves in Hydrochloride acid and why not in water?

Buprenorphine is nitrogen containing organic compound which is basic in nature. It dissolves in Hydrochloric acid being basic in nature and forms a salt with it. Usually organic basic compounds are insoluble in water or very slightly soluble in water.

iii) Whether the combination of Buprenorphine and Hydrochloric acid is a compound or a mixture.

The combination of Buprenorphine and Hydrochloric acid is a Chemical reaction (in animalcular proportion) forming Buprenorphine Hydrochloride which is a compound having molecular formula $C_{29}H_{41}NO_4 \cdot HCl$ and not a mixture.

iv) Can Buprenorphine Hydrochloride be called a solution of Buprenorphine salt?

Buprenorphine Hydrochloride cannot be called a solution of Buprenorphine, it is a salt of Buprenorphine which is white or almost white crystalline powder. From the aforesaid experts' opinions, it can be safely concluded that Buprenorphine Hydrochloride is a salt of Buprenorphine. This being the case Buprenorphine Hydrochloride would be a 'psychotropic substance' under the NDPS Act.

A7. The learned counsel appearing for the petitioners referred to some decisions to stress the point that Buprenorphine Hydrochloride was neither a 'narcotic drug' nor a 'psychotropic substance'. He firstly relied upon *Deep Kumar v. State of Punjab (PandH): 1997 (2) R C R 502* to submit that Buprenorphine Hydrochloride was not a psychotropic substance. Paragraph 13 of this decision of the Punjab and Haryana High Court reads as under:-

'13. Now we are left with parcels Nos. 1 and 6 which were found to contain Binorfin and Norphen injections. On an analysis each injection in parcel No.1 was found to contain 0.32 mg of Buprenorphine. The contents of parcel No.6, on analysis were found to contain 0.3 mg of Buprenorphine. This psychotropic substance does not fall within the ambit of Schedule I annexed to the Narcotic Drugs and Psychotropic Substances Rules, 1985, but is found to contain in Schedule III thereof. This substance, be ingot covered by Schedule I of the Rules, shall be governed by the Drugs Act and Rules framed hereunder. The quantity of Buprenorphine has been

found within the permissible limit and the petitioners were possessed with a valid Drug License to keep and dispense such injections. therefore, it cannot be said that the possession of Binorfin and Norphen injections was in contravention of section 22 of the Narcotic Act.'

This decision itself proceeds on the basis that it is a psychotropic substance. It is a different matter that, as no reference to buprenorphine was found in Schedule I to the NDPS Rules, the court held that it would be governed by the D and C Act and Rules. That is an aspect which I shall discuss in answer to question No.2. For the present, this much is clear that Buprenorphine Hydrochloride is a psychotropic substance within the meaning of the NDPS Act.

A8. The next case referred to by the counsel for the petitioners was the decision of a learned single judge of the Madras High Court in K.R. Nagappan v. State: 1996 (1) Crimes 502. In that case there was a recovery of 55 ampoules of 2 ml Tidigesic injections. Each ml whereof contained 0.3 mg Buprenorphine Hydrochloride. The appellant therein had been convicted for the offence under Section 8 read with section 21 of the NDPS Act. After examining the definitions of 'opium' and 'opium derivate'in section 2 and section 2(xvi) of the NDPS Act as well as the Explanationn appended to section 2 pertaining to the above definitions, the court held:-'A casual reading of the definitions given above in Section 2 of the NDPS Act, clinches the fact that such of the opium and opium derivatives containing not more than 0.2 per cent of morphine have been excluded from the narcotic and psychotropic substances. 0.2 per cent of morphine cannot be equated with the 0.3 mg of Buprenorphine found in each of the 55 ampoules which is conspicuously and manifestly far lesser than 0.2 per cent of morphine.' This decision also would be of no help to the petitioners. The allegation there was of the commission of an offence under section 21 of the NDPS Act which deals with 'narcotic drugs'. In the present case the petitioners have all been prosecuted for allegedly committing offences under section 22 of the NDPS Act which relates to 'psychotropic substances'. The definitions for narcotic drugs and psychotropic substances are entirely different. therefore, the decision in K. R. Nagappan (supra) also cannot be pressed in aid of the petitioners' submissions.

A9. Lastly, the learned counsel for the petitioners referred to the decision of a learned single judge of the Punjab and Haryana High Court in the case of Amtrak Singh v. The State of Punjab: 1996 (2) All I C L R 714. This was a case where the petitioner having been found to be in possession of 35 bottles of PHENSEDYL (a cough medicine) of 125 ml each was being prosecuted for an offence under section 21 of the NDPS Act. The samples taken disclosed that every 5 ml of the medicine contained 9.5 mg of Codeine Phosphate. In this context the Court observed:-

'9. The learned State Counsel has argued that the preparation in question is being widely used for intoxicating purposes by students, teenagers and other addicts; that the petitioner was indulging in the sale of such drugs without prescription of the doctor to the addicts and he could not produce the purchase bill/cash memo and the license required for the sale of such item, and as such the petitioner is liable under section 21 of the Act.

10. The aforesaid argument of the learned State Counsel is misconceived. If the petitioner sells any drug to a person in contravention of license granted to him or that he fails to produce the bill/cash memo or the license for the sale of such item, he can be proceeded against under the provisions of the [Drugs and Cosmetics Act, 1940](#) by the Drug Inspector in accordance with the provisions of the said Act. Section 21 of the Act in hand is not attracted for such violation or contravention.'

This case is clearly distinguishable on facts. In any event, like the decision in K. R. Nagappan (supra) this case also related to section 21 of the NDPS Act.

While on the subject of precedents, it must be noted that Buprenorphine Tidigesic injections have been held to be psychotropic substances by the Supreme Court in Hussein v. State of Kerala: 2000 (4) Crimes 144 (SC) .

Re: Question No.2:

A10. So, it is clear that buprenorphine hydrochloride is a psychotropic substance within the meaning of the NDPS Act. But, would that in itself make the possession, sale or transportation of buprenorphine hydrochloride injections an offence under

the NDPS Act, punishable under section 22 thereof? The answer is in the negative. In the context of section 21 of the NDPS Act which is an analogous provision in respect of 'narcotic drugs', the Supreme Court, in the case of *Sajan Abraham v. State of Kerala*: : 2004 CriLJ1757 . It is thus apparent that what is made punishable under Section 21 is possession, sale, purchase, etc. of the drugs and preparations mentioned therein in contravention of any provision of the Act or any rule or order made or condition of license granted there under. Obviously, therefore, if any rule permits a person to possess any psychotropic substance within the limits specified under the rule and subject to such conditions as the rule may prescribe, such a person cannot be held guilty of the offence under Section 21 of the Act if it is shown that his possession is not in contravention of such rule.'

This would apply equally to the offence punishable under section 22 of the NDPS Act in relation to psychotropic substances. This is clear as, in the case of *Ouseph v. State of Kerala*: : (2004)4SCC446 , the Supreme Court had observed that [at page 447]:-

'If it is a psychotropic substance, possession of it would become an offence only if it was in contravention of the Rules prescribed.' And, in *Hussain v. State of Kerala*: : 2000(72)ECC14 , the Supreme Court had already held that:-'If it was 'psychotropic substance' possession of the same would amount to an offence only if it was in contravention of Section 8 of the Act. That section shows that no person shall possess any psychotropic substance except for medical or scientific purposes and in the manner and to the extent provided by the provisions of this Act or the Rules or orders made there under.'

Therefore, an examination of section 8 of the NDPS Act and the provisions of Chapter VII of the NDPS Rules is called for. Firstly, Section 8 of the NDPS Act reads as under:-

'8. Prohibition of certain operations.-- No person shall--

(a) cultivate any coca plant or gather any portion of coca plant; or

(b) cultivate the opium poppy or any cannabis plant; or

(c) produce, manufacture, possess, sell, purchase, transport, warehouse, use, consume, import Interstate, export Interstate, import into India, export from India or transship any narcotic drug or psychotropic substance,

except for medical or scientific purposes and in the manner and to the extent provided by the provisions of this Act or the rules or orders made there under and in a case where any such provision, imposes any requirement by way of license, permit or authorisation also in accordance with the terms and conditions of such license, permit or authorisation:

Provided that, and subject to the other provisions of this Act and the rules made there under, the prohibition against the cultivation of the cannabis plant for the production of ganja or the production, possession, use, consumption, purchase, sale, transport, warehousing, import Interstate and export Interstate of ganja for any purpose other than medicinal and scientific purpose shall take effect only from the date which the Central Government may, by notification in the Official Gazette, specified in this behalf.

Provided further that nothing in this section shall apply to the export of poppy straw for decorative purposes'

Section 8, which is relevant for our purpose as it deals with psychotropic substances, prohibits the manufacture, possession, sale, use etc., of any psychotropic substance 'except for medical or scientific purposes and in the manner and to the extent' provided by the provisions of the NDPS Act or NDPS Rules or orders made there under. This means that while there is a general prohibition against the manufacture, possession, sale, use etc., of a psychotropic substance, if the same is a medicine and is to be used for a medical purpose then the manner and extent of its manufacture, possession, sale, use shall be as provided in the NDPS Act or NDPS Rules or orders made there under. We must remember that buprenorphine hydrochloride I.P. is a Schedule Drug within the meaning of the D and C Act and Rules. Its manufacture, sale etc., is regulated by the D and C Act and D and C Rules. Coming back to the NDPS Act, I find that in the case of a medication, which also happens to be a psychotropic substance within threading of the NDPS Act, its 'extent and manner' of use etc., would be

governed by the other provisions of the NDPS Act or NDPS Rules.

A11. Section 9 of the NDPS Act empowers the Central Government to permit, control and regulate, inter alia, the manufacture, possession, sale, transportation of psychotropic substances. The NDPS Rules have been formulated by the Central Government in exercise of that power. Chapter VII of the NDPS Rules deals with 'Psychotropic Substances'. Rules 64 to 67 fall under this Chapter VII. Rule 64 prescribes the general prohibition. It provides that --

'No person shall manufacture, possess, transport, import inter-state, export inter-state, sell, purchase, consume or use any of the psychotropic substances specified in Schedule I.' It is to be noted that this 'Schedule I' is different to the Schedule to the NDPS Act. This Schedule I is appended to the NDPS Rules and is in two parts - (I) Narcotic Drugs and (II) Psychotropic Substances. We are concerned with psychotropic substances. There is a list of 33 specific psychotropic substances with entry no. 34 being 'Salts and preparations of above'. It is significant to note that neither buprenorphine hydrochloride nor buprenorphine find mention in this list. This clearly means that Buprenorphine Hydrochloride is not included in Schedule I to the NDPS Rules and therefore the general prohibition contained in Rule 64 of the NDPS Rules does not apply to it². Consequently, rules 65 to 67, which also have reference to psychotropic substances specified in the said Schedule I, would also not be applicable in respect of Buprenorphine Hydrochloride³. In this connection, it is pertinent to point out that there are several psychotropic substances which find place both in the Schedule to the NDPS Act and in Schedule I to the NDPS Rules. For example: Methaqualone⁴, Delorazepam⁵, Ketazolam⁶, Loprazolam⁷, Pipradrol⁸, Tetrazepam⁹. At the same time, there are others like Buprenorphine¹⁰, Amphetamine¹¹, Bromazepam¹², Lorazepam¹³, Phenobarbital¹⁴ and Pemoline¹⁵ which, though specified in the Schedule to the NDPS Act, do not find mention in Schedule to the NDPS Rules. Clearly, by conscious design, all psychotropic substances mentioned in the Schedule to the NDPS Act have not been listed in Schedule I to the Rules. The prohibition contained in Rule 64 of the NDPS Rules applies only to those psychotropic substances which are specified in Schedule I to the NDPS Rules. In other words, the prohibition of Rule 64 of the NDPS Rules is not applicable to

those psychotropic substances, which, although they are listed in the Schedule to the NDPS Act, are not part of the listed psychotropic substances in Schedule I to the NDPS Rules. It may be mentioned here that the Supreme Court, in the aforementioned decisions¹⁶, was not called upon to examine this aspect of the matter, namely, whether Rule 66 of the NPS Rules applied to all psychotropic substances or only those specified in Schedule I to the NDPS Rules. It is, therefore, open to this Court to consider and decide this aspect of the matter.

Rule 65(1), *inter alia*, provides that the manufacture of any psychotropic substance other than those specified in Schedule I shall be in accordance with the conditions of license granted under the D and C Rules and D and C Act. In other words, insofar as the psychotropic substances not mentioned in Schedule I to the NDPS Rules but mentioned in the Schedule to the NDPS Act are concerned, their manufacture shall be governed by the D and C Act and Rules and not by the NDPS Act or NDPS Rules. Rule 66 relates to possession etc., of psychotropic substances. Sub-Rule (1) thereof provides that no person shall possess 'any psychotropic substance' for any of the purposes covered by the D and C Rules, unless he is lawfully authorised to possess such substance for any of the said purposes under the NDPS Rules. The expression 'any psychotropic substance' obviously has reference to those listed in Schedule I to the NDPS Rules. Rule 64 is the governing rule in Chapter VII of the NDPS Rules. When a psychotropic substance does not find mention in Schedule I to the NDPS Rules, the prohibition *qua* possession contained in Rule 64 does not apply. That being the case, in respect of such a psychotropic substance, Rule 66 would also not apply as it has reference to only those psychotropic substances which are included in Schedule I to the NDPS Rules. Rule 67 of the NDPS Rules relates to transport of psychotropic substances. It is expressly subject to the provisions of Rule 64 and clearly has reference to the transport, import inter-state or export inter-state of those psychotropic substances which are included in Schedule I to the NDPS Rules. The rule would have no applicability in respect of those psychotropic substances which are not to be found in Schedule I to the NDPS Rule. Clearly, then, inasmuch as Buprenorphine Hydrochloride is not included in Schedule I to the NDPS Rules, its manufacture, possession, sale, transport would neither be prohibited nor regulated by the NDPS Rules and consequently by the NDPS Act. It

being Schedule H drug would fall within the rigours of the D and C Act and Rules.

Re: 'Small quantity', 'Commercial quantity'

A12. For the sake of completeness, another aspect of the matter which, although academic in the context of the answer to question 2 above, requires some clarification (before I discuss the individual merits of each of the applicants) is with regard to the status of 'small quantity' and 'commercial quantity'. These expressions are defined under Sections 2 and 2(vii-a) of the NDPS Act, which read as under:-(xxiii-a) 'small quantity', in relation to narcotic drugs and psychotropic substances, means any quantity lesser than the quantity specified by the Central Government by notification in the Official Gazette.'

(vii-a) 'commercial quantity' in relation to narcotic drugs and psychotropic substances, means any quantity greater than the quantity specified by the Central Government by notification in the Official Gazette.'

By a Notification dated 19th October, 2001 the Central Government specified the 'small quantity' and 'commercial quantity' of each of the Narcotics Drugs/Psychotropic substances listed therein. In the table appended to the said Notification, at Entry No. 169, Buprenorphine has been specified and the small quantity has been mentioned as 1 gram whereas the commercial quantity has been specified as 20 grams. However, there is no specific mention of Buprenorphine Hydrochloride. The said Entry 169 and Entry 239, which, apparently, is a residual entry, read as:-

Sl.No	Name of Narcotic Drug and Psychotropic Substance [International non-proprietary name (INN)]	Other non-proprietary name	Chemical Name	Small quantity (in gm.)	Commercial Quantity (In gm./kg.)
1	169	Buprenorphine	21-cyclopropyl-7- α -[(S)-1 hydroxy-1,2 2-trimethyl'propyl]-6, 14-endo, ethano-6, 7,8,14-tetrahydrooripavine	3. 20gm	

Any mixture or preparation that of with or without a neutral material, of any of the above drugs.

Lesser of the small quantity between the quantities given against the respective narcotic drugs or psychotropic substances mentioned above forming part of the mixture.

Lesser of the commercial quantity between the quantities given against the respective narcotic drugs or psychotropic substances mentioned above forming part of the mixture.' Note 1 to the said table reads as under: - 'Note.-(1) The small quantity and the commercial quantity given against the respective drugs listed above apply to isomers, within specific Chemical designation, the esters, ethers and salts of these drugs, including salts of esters, ethers and isomers, whenever existence of such substance is possible.' Upon a collective reading of the said Note 1, entry 239 and entry 169 of the said table it becomes clear that the small quantity for Buprenorphine Hydrochloride is also 1 gram and the commercial quantity is 20 grams as in the case of Buprenorphine, of which it is a salt.

A13. Finally, it must be noted that Buprenorphine Hydrochloride I.P. is also a medication and is used as a pain reliever. Recently it is also being used to treat opiate addiction (such as addiction to heroin). It has legitimate uses as an analgesic and for de-addiction. However, it is also capable of misuse being a psychotropic substance. Perhaps because of this reason, it was left out of Schedule I to the NDPS Act but is very much regulated under the D and C Act and Rules.

This concludes the discussion on the common issues. I shall now take up each application for grant of bail.

Bail Application No. 73/2005 Rajinder Gupta (Petitioner)

B1. The petitioner is a partner in the firm known as M/s. A.D.S. Associates. The allegation against the petitioner is that he, as a partner of the said firm sold 2,61,000 ampoules of Buprenorphine Hydrochloride Injections under the brand name Bunogesic which he had allegedly received from M/s Pharma Deal Agencies, 487/35, National Market, New Delhi. It is further alleged that the petitioner had not maintained any record by way of consignment Form-6, as required under Rules 66 and 67 of the NDPS Rules in respect of sales of the

aforesaid quantity of ampoules of injections. Accordingly, it is alleged that the petitioner has contravened the provisions of Section 8(c) of the NDPS Act which is an offence punishable under Section 22(c) of the NDPS Act. The petitioner was arrested on 13.10.2004 and is in judicial custody since then. No recovery of the said Buprenorphine Hydrochloride Injections was, however, made from the petitioner. According to the petitioner these injections are covered under Schedule 'H' of the Drugs and Cosmetics Rules, 1945. The petitioner also contends that these Buprenorphine Hydrochloride Injections conform to the standard laid down by the Indian Pharmacopoeia. The petitioner also contends that the said ampoules were labeled in accordance with Rule 97 of the Drugs and Cosmetics Rules, 1945 and bore the symbol 'Rx'17 on the top left corner of the label. They also contained the usual Schedule 'H' drug warning as under:-

'Schedule H drug' Warning: To be sold by retail on the prescription on a Registered Medical Practitioner only.'

B2. The petitioner further submitted that all purchase and supplies have been made through proper documents, as required in the normal course of business. It is further contended that the petitioner has a drug license under the Drugs and Cosmetics Act and Rules. The license bears No. DL-2(2380) 20B and 21B. The license in Form 20B is issued under Rule 61(1) of the Drugs and Cosmetics Rules, 1945 whereas the license in Form 21B is issued under Rule 61(2) of the Drugs and Cosmetics Rules, 1945. Copies these licenses have been filed at pages 17 and 18 of the paper book and they clearly indicate that the Firm ADS Associates is licensed to sell, stock or exhibit or offer sale or distribute by wholesale the drugs specified therein. Schedule 'H' Drugs have not been excluded and, therefore, according to the petitioner the said Firm had a license to deal in and sell the said Buprenorphine Hydrochloride Injections. The said injections bearing the branded name 'Bunogesic' were of 2 ml each. And, each ml thereof contained Buprenorphine Hydrochloride IP equivalent to Buprenorphine Hydrochloride 0.3 mg and water for injection. These injections were manufactured by Rusan Health Care Private Limited which is a licensed manufacturer. It is further dated that the said Rusan Health Care Private Limited had informed the petitioner firm on 21.10.2004 that they had deleted their product under the name 'Bunogesic' and

requested the petitioner firm to return the unsold stock lying with them. It is stated that the petitioner thereafter never dealt with the said product of the said manufacturer. It is further stated that the petitioner is a bona fide licensed trader and has an absolutely clean and un-blemished record. He is authorised to sell and deal in Schedule 'H' medicines which includes Buprenorphine Hydrochloride IP injections.

B3. The allegation against the petitioner is that he contravened Rules 66 and 67 of the NDPS Rules and thereby contravened section 8(c) of the NDPS Act and, as a result thereof, became liable for punishment under section 22(c) of the NDPS Act. As indicated above, Buprenorphine Hydrochloride is a Schedule H drug under the D and C Act and Rules and, though it is a psychotropic substance under the NDPS Act, it is not included in Schedule I to the NDPS Rules. That being the case, its manufacture, possession or sale is not prohibited. As such, there is no contravention of the provisions of the NDPS Rules. Consequently, the offence under section 8 of the NDPS Act is not made out. Obviously, punishment under section 22 of the NDPS Act is also not attracted.

B4. Clearly, in these circumstances as no offence under the NDPS Act is made out, the petitioner would be entitled to bail. Accordingly, he is directed to be released on bail on furnishing a personal bond in the sum of Rs. 25,000/- with one surety of the like amount to the satisfaction of the concerned trial court.

Bail Application 53/2005 Mohd. Shehber Khan (petitioner)

C1. In this case the petitioner is in custody since 13.10.2003 in respect of having allegedly committed offences punishable under section 22 and 29 of the NDPS Act. The allegations against him are that he was in conspiracy with one Raj Kumar Arora in the sale of Buprenorphine Hydrochloride IP injections and that from the premises of Raj Kumar Arora, 40,001 Buprenorphine Hydrochloride injections were recovered. No recovery was affected from the petitioner of any kind. The recovered drug, according to the petitioner, is covered by the Indian Pharmacopoeia and is a Schedule-H Drug under the Drugs and Cosmetics Rules, 1945. It is stated by the petitioner that the co-accused Devang Bipin Parikh has already been granted bail by an order dated 11.1.2005.

In the complaint, it is stated that the premises of one Raj Kumar, proprietor of Kanishka Cargo Service was searched and a recovery of 25 corrugated card board cartons was made there from. These cartons were said to contain glass ampoules containing transparent water coloured liquid. Apart from the above, it is alleged that the officers also recovered a single ampoule apparently of the same size and shape as the unlabelled ampoules recovered from 25 cartons and also having similar single red coloured ring marking round the neck of the ampoule containing apparently similar transparent water coloured liquid and having a label with the following description:-Rx 2 ml.

BUPRENORPHINE HYDROCHLORIDE INJECTION I.P.

BUPRIGESICNEON LABORATORIES LIMITED Mfg. Lic No. 752B. No. 19559

995 printed paper sheets were also found lying on the side of the table and each sheet contained the following description:-Rx 2 ml.

BUPRENORPHINE HYDROCHLORIDE INJECTION IPBUPRIGESICNEON
Laboratories LIMITED Mfg. Lic. No. 752B.No.

It is alleged that the said Raj Kumar Arora could not produce any authorisation for possession of the unlabelled glass ampoules.

C2. Nothing was recovered from the petitioner. Furthermore, the entire allegation is with regard to the alleged recovery of Buprenorphine Hydrochloride made from one Raj Kumar Arora. It has already been indicated above that Buprenorphine Hydrochloride is a Schedule H drug under the D and C Act and Rules and, though a psychotropic substance under the NDPS Act, it is not included in Schedule I to the NDPS Rules. That being the case, its manufacture, possession or sale is not prohibited. As such, there is contravention of the provisions of the NDPS Rules. Consequently, the offence under section 8 of the NDPS Act is not made out. Obviously, punishments under sections 22 or 29 of the NDPS Act are also not attracted.

C3. In these circumstances, as no offence under the NDPS Act is made out, the petitioner would be entitled to bail. Accordingly, he is directed to be released on

bail on furnishing a personal bond in the sum of Rs. 25,000/- with one surety of the like amount to the satisfaction of the concerned trial court.

Bail Application 64/2005 Vijay Kumar Mittal (Petitioner)

FIR No. 79/2004 dated 13/10/2004 under sections 22, 29 NDPS Act, 1985 P.S. Narcotics Branch

D1. The case for the prosecution is that a secret information was received in which it was alleged that one Mahesh and one Surinder were going to purchase a huge quantity of Buprenorphine from the petitioner without bill and were further going to sell the same to the retailers and small chemists etc. A raid was allegedly conducted and 2325 ampoules of Buprenorphine Hydrochloride 'Bunogesic' and 3950 ampoules of Buprenorphine Hydrochloride were allegedly recovered from Mahesh and Surinder respectively. It is alleged that 3950 ampoules which were recovered were purchased from the petitioner and each of these ampoules contained 2 ml. of psychotropic substance. The other 2325 ampoules were alleged to have been purchased from one Mr Jain. On the basis of the disclosure statements of Mahesh and Surinder, the present petitioner (Vijay Kumar Mittal) was arrested on 14.10.2004 for allegedly selling the injections without bill to these two persons. It is stated that the petitioner is an income tax payer and carries on business of sale and purchase of medicines under the trade name of 'Mittal Medical Agency'. The petitioner holds a valid license No. 26 (1102) 20B and 21B which was issued on 29.12.1999 and the said license has been renewed up to 31.12.2007. The said firm is authorised under the license to sell, stock or exhibit or offer for sale or distribute by wholesale Buprenorphine Hydrochloride Drug in addition to other drugs permitted therefrom. It is stated that the charge-sheet has been filed in this case and the petitioner has been arrested solely on the basis of disclosure statements made by Mahesh and Surinder. It is the petitioner's contention that no drug of any kind has been sold by the petitioner to the said Mahesh or Surinder and the case is entirely false and fabricated. It is further contended that 3950 ampoules are alleged to be related to the petitioner. Each ampoule contains 2 ml. And, therefore, the total quantity comes to 7900 ml. The Buprenorphine Hydrochloride contained in each ml. is 0.3 mg (or 0.0003 gm).

therefore, the total content in respect of these 3950 ampoules would come to $7900 \times 0.0003 = 2.37$ gms which is far below the commercial quantity of 20 gms.

D2. I have already held that Buprenorphine Hydrochloride is beyond the pale of Chapter VII of the NDPS Rules and therefore, it being a Schedule H drug under the D and C Act and Rules, the offence under section 8 is not made out. Consequently, punishments under section 22 or 29 of the NDPS Act would not be attracted. Additionally, the petitioner is being roped in only on the basis of disclosure statements of the said Mahesh and Surinder. As indicated in *Manoj Kumar Gupta v. State N.C.T. Of Delhi*: 2003 [1] JC 205, the disclosure statement of a co-accused is not substantive evidence. Furthermore, assuming that an offence under the NDPS Act was, prima facie, made out, the quantity linked to the present petitioner is only 2.37 gm, much lower than the commercial quantity of 20 gm. Accordingly, even in this assumed scenario, the rigours of section 37 of the NDPS Act would not apply.

D3. In view of all these circumstances the petitioner would be entitled to bail. Accordingly, he is directed to be released on bail on furnishing a personal bond in the sum of Rs. 25,000/- with one surety of the like amount to the satisfaction of the concerned trial court.

Bail Application 2062/2005 Sawinder Singh Kohli (Petitioner)

E1. The petitioner is alleged to have committed offences punishable under sections 22, 23, 28 and 29 of the NDPS Act. It is alleged that on 9.5.2004, the petitioner was going to Tehran via Dubai on Flight No. EK-513. It is further alleged that he was stopped at the departure hall of IGI Airport, New Delhi and 1091 ampoules of 2 ml. each of Buprenorphine Hydrochloride Injection IP under the printed name of Buprenorphine Hydrochloride are alleged to have been recovered from him. It is further alleged that the customs officer recovered a further 6144 ampoules of Buprigesic from flat No. WP-207A Pitampura, Delhi, which belongs to the brother-in-law of the petitioner.

E2. The petitioner is aged about 70 years and is said to be suffering from heart problems. It is further contended that he was taking treatment in Iran and is

undergoing such treatment now in Tihar Jail. Only 1091 ampoules of Buprenorphine Hydrochloride are alleged to have been recovered from the petitioner. therefore, taking the content of each 2ml ampoule (as per the complaint itself) to be 0.6 mg of Buprenorphine Hydrochloride, the recovery from the petitioner is only of $1091 \times 0.6 = 658.2$ mg or 0.682 gm of Buprenorphine Hydrochloride which amount is even smaller than the specified small quantity of 1 gm. Moreover, even if all the ampoules are taken to be recovery from the petitioner they would total to 7235 ampoules of 2 ml. each. That would translate to a content of only 4.341 gms of Buprenorphine Hydrochloride and not 14.5 kg as erroneously calculated by the learned Additional Sessions Judge in his order dated 7.8.2004 whereby the petitioner's bail application was rejected. Even this quantity is far below the commercial quantity of 20 gm.

E3. I have already held that Buprenorphine Hydrochloride is beyond the pale of Chapter VII of the NDPS Rules and therefore, it being a Schedule H drug under the D and C Act and Rules, the offence under section 8 is not made out. Consequently, punishments under section 22, 23, 28 or 29 of the NDPS Act would not be attracted. Furthermore, assuming that an offence under the NDPS Act was, prima facie, made out, the quantity linked to the present petitioner is only 4.341 gm, much lower than the commercial quantity of 20 gm. Accordingly, even in this assumed scenario, the rigours of section 37 of the NDPS Act would not apply.

E4. In view of all these circumstances the petitioner would be entitled to bail. Accordingly, he is directed to be released on bail on furnishing a personal bond in the sum of Rs. 25,000/- with one surety of the like amount to the satisfaction of the concerned trial court.

Bail Application 115/2005 Amit Dawar (Petitioner) FIR No. 86/2003 dated 3/10/2003 under sections 22, 29 NDPS Act P.S. Narcotics Bureau

F1. The case of the prosecution is that on 21.7.2003 the premises of M/s Gill Sandhu, Haryana Transport Com. At 3902 Mori Gate, Delhi was searched and 40 Cartons of 'Norphin' (Buprenorphine Hydrochloride) injections purported to have been manufactured by M/s Unichem Laboratories Ltd. are said to have been recovered. It is alleged that the Manager of the said Transport Company informed

the Drug Inspector that the said 'Norphin' injections were booked for Delhi in their Chandigarh Branch and no claimant came forward to receive the consignment of the above said injections. Samples of the said 'Norphin' injections were sent by the Drug Inspector to the manufacturer Co. i.e. Unichem Laboratories Ltd. which confirmed that it was their product was of standard quality. On 1.8.2003, it is alleged, the proprietor of Surya Pharmaceutical, Jalandhar claimed the consignment of the said 'Norphin' injections and submitted the purchase bill issued from M/s Laxmi Medical Hall, Chandigarh. On 1.10.2003 one Pravin Kumar alias Sonu proprietor of Surya Pharmaceuticals was arrested and he allegedly made a disclosure statement alleging therein that the present petitioner (Amit Dawar) was the financier of the said consignment of Buprenorphine Hydrochloride injections. On the basis of this disclosure statement, the petitioner was arrested on 12.10.2003. No recovery was made from the present petitioner Amit Dawar and it is the petitioner's case that at the maximum even if the entire prosecution case were to be believed, only the commission of an offence punishable under Section 27 of the Drug and Cosmetics Act, 1940 is made out and that the maximum imprisonment therefor is three years imprisonment and the same is triable by the Court of the Metropolitan Magistrate.

F2. I have already held that Buprenorphine Hydrochloride is beyond the pale of Chapter VII of the NDPS Rules and therefore, it being a Schedule H drug under the D and C Act and Rules, the offence under section 8 is not made out. Consequently, punishments under section 22 or 29 of the NDPS Act would not be attracted. Nothing was recovered from the petitioner. And, the petitioner is being roped in only on the basis of an alleged disclosure statement of the said Pravin Kumar alias Sonu proprietor of Surya Pharmaceuticals. As indicated in *Manoj Kumar Gupta v. State N.C.T. Of Delhi*: 2003 [1] JCC 205, the disclosure statement of a co-accused is not substantive evidence.

F3. In view of all these circumstances the petitioner would be entitled to bail. Accordingly, he is directed to be released on bail on furnishing a personal bond in the sum of Rs. 25,000/- with one surety of the like amount to the satisfaction of the concerned trial court.

Bail Application 205/2005 Raj Kumar Arora (petitioner)

G1. The petitioner is alleged to have contravened Rule 66 of the NDPS Rules and thereby committed offences punishable under sections 22 and 29 of the NDPS Act. The petitioner states that he is a licensed Customs Clearing House Agent and is a proprietor of M/s Kanishka Cargo Services having its office at 198, Office Complex, Jhandewalan Cycle Market, New Delhi. The case of the prosecution is that a raid was conducted on the office premises of the petitioner on 27/28.9.2003 and alleged recovery of 40,001 glass ampoules containing water coloured liquid preparation suspected to be injectable preparation of Buprenorphine Hydrochloride is said to have been recovered. The petitioner was arrested on 27/28.9.2003 and has been in judicial custody since then. The petitioner states that he is not a beneficiary, manufacturer or seller of the medicinal drugs and is only a licensed Customs House Agent. The petitioner was handling consignments of its clients including M/s Sarvodaya Enterprises which is owned by c-accused Devang Bipin Parikh who has been granted bail by this Court on 11.1.2005. Various medical consignments have been cleared from Customs by the petitioner on behalf of the said client for export as well as import.

G2. As indicated above, Buprenorphine Hydrochloride is beyond the pale of Chapter VII of the NDPS Rules and therefore, it being a Schedule H drug under the D and C Act and Rules, the offence under section 8 is not made out. Consequently, punishments under section 22 or 29 of the NDPS Act would not be attracted. Moreover, the petitioner was only a Customs House Agent who cleared medical consignments on behalf of his clients.

G3. In view of all these circumstances the petitioner would be entitled to bail. Accordingly, he is directed to be released on bail on furnishing a personal bond in the sum of Rs. 25,000/- with one surety of the like amount to the satisfaction of the concerned trial court.

H1. It is made clear that all observations made in this order, whether common to all the applications or specific to each of the applicants, are only prima facie in nature. They are only for the purposes of consideration of the aforementioned bail applications and are not to be regarded at the time of trial of the respective cases.

All the applications stand disposed of.

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