IN THE HIGH COURT OF JUDICATURE AT MADRAS

RESERVED ON : 27.08.2020
PRONOUNCED ON : 13 .10.2020

CORAM
THE HONOURABLE MR.JUSTICE M.NIRMAL KUMAR

Crl.O.P.No.21289 of 2014 and
Crl.M.P.No.1 of 2014

1. M/s.Brooks Hi-Tech Pvt. Ltd.,
Rep. by its Director,
New no.7, Old No.4,
Wason Street, T.Nagar,
Chennai-600 017.

2. Mr.Nimish C.Tolia,
Director,
Having Office at,
New no.7, Old No.4,
Wason Street, T.Nagar,
Chennai-600 017. ... Petitioners/A1 & 2

Vs.

Union of India,
Rep. by the Drugs Inspector,
Office of the Deputy Drugs Controller (India),
Central Drugs Stands Control Organization,
South Zone, 2nd Floor, Shastri Bhavan Annexe,
Chennai-600 006. ... Respondent/Complainant

PRAYER: Criminal Original Petition is filed under Section 482 of the Code of Criminal Procedure, to call for the records in and connected with C.C.No.43 of 2014 on the file of the Court of XV Metropolitan Magistrate, George Town, Chennai and quash the same.

For Petitioner :Mr.B.Satish Sundar
For Respondent :Dr.D.Simon,
Central Government Standing Counsel

ORDER

This Criminal Original Petition has been filed to quash the proceedings in C.C.No.43 of 2014, pending on the file of the XV Metropolitan Magistrate Court, George Town, Chennai.

2.The respondent/the Drug Inspector, Union of India, Central Drugs Standard Control Organization, South Zone, 2nd Floor, Chennai, lodged a complaint to the Court below against the petitioners, for offence under Sections 13(1)(b) r/w 10(c) and 18(b) of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as 'Act').

3.The gist of the complaint is that the respondent, who is a notified Drug Inspector lodged a complaint against the petitioners/A1 and A2 for violation of Sections 10(c) and 180(b) of the Drugs and Cosmetics Act, 1940. As per Act, an importer, who intends to import a drug into India should apply for license to the Drugs Controller General (India) under Form-10. In the application, the importer has to declare the nature of the drug and the particulars of the manufacturer of the drug. Thereafter, the Drugs Controller General (India) issues license under Form-10. The importer, who is holding license under Form-10, can only import drug directly from the foreign drug manufacturer. In this case, the petitioners has not obtained license under Form-10 and has imported Albendazole CP 2000 from M/s.Jiangsu Guotai International Group Winsun Import & Export Company Limited, China against invoice No.GF DIG09024, dated 15.03.2009. The imported 2000 kgs (80 kgs drums) in two batch numbers were sold to 16 buyers on various dates from 22.09.2009 to 17.06.2010. One of the buyer viz., M/s.Vidya Pharmaceutical Private Limited, Thane had purchased 300 kgs of Albendazole CP 2000 from the petitioners.

4.The Drug Inspector, Central Drugs Standard Control Organization (CDSCO), West Zone, Mumbai conducted inspection in the premises of M/s.Vidya Pharmaceuticals Private Limited, Thane and took samples of the drug Albendazole CP 2000 and sent for testing/analysis to the Central Drugs Laboratory, Government of India, Kolkata. The Central Drugs Laboratory, Government of India, Kolkata, by report dated 15.01.2010 found the samples does not confirm to USP with respect to the test for 'Chromatographic Purity'. Thereafter, the Deputy Drugs Controller (India), CDSCO West Zone, Mumbai informed the same to the Deputy Drugs Controller (I), CDSCO (South Zone), Shastri Bhawan, Annexe 26, Haddows Road, Chennai about M/s.Vidya Pharmaceuticals, procurement of drugs from the 1st petitioner, by communication dated 20.12.2010. Investigation was carried out with the petitioners and it was found that the petitioners imported 2000 kgs of Albendazole CP 2000 against the Bill of Entry No.223821, dated 26.05.2009, was without clearance by the Assistant Drugs Controller (India), Chennai Port and without license under Form-10 and it was further found that there is no stock of imported drugs available and the entire imported drugs were sold. A show cause notice was issued to the petitioners on 10.03.2011 for contravention of Section 10(c) and 18(b) of the Act. On 11.04.2011, the petitioners sent an explanation.

5.The respondent confirmed from the Customs Department and found that the petitioners assessed the goods on 27.05.2009 and cleared the same on 05.06.2009. This information was informed by the Assistant Drugs Controller (I), Chennai Port to the Deputy Drugs Controller (I), CDSCO, South Zone, Chennai by letter dated 21.06.2011. Finding the petitioners contravening the provisions and Rules of the Act and on obtaining permission to launch prosecution on 29.06.2012 by nominating law officer on 03.07.2012, the respondent lodged a complaint dated 12.07.2013 against the petitioners, against which the present quash petition.

6.The learned counsel for the petitioners submitted that the 1st petitioner placed orders with its overseas supplier namely M/s.Jiang Su Guotai International Group Winson Import and Export Limited, China for supply of 2000 kgs of substance known as Albendazole CP 2000. The learned counsel further submitted that the supplier raised a commercial invoice for USD 29000 for the supply of goods. Thereafter, the goods were enlisted in the packing list, wherein it was mentioned that the date of manufacture as December 2008 with expiry date as December 2012. The supplier in China furnished a Certificate of Analysis, which indicates that the goods confirm to Pharmacopoeia standards. The goods were accompanied by a Certificate of Origin, after proper insurance of cargo and Bill of Lading. On arrival of the goods, the 1st petitioner filed the Bill of Entry to the customs authorities for clearance of the goods and the goods were cleared. After clearance from the customs, the goods were sold by the 1st petitioner under taxable invoices to manufacturers of animal feed and the same were effected between September 2009 and June 2012.

7.The learned counsel for the petitioners further submitted that on 22.12.2010, the officers attached to the respondent, visited the premises of the petitioners and directed the petitioners to produce invoices. The invoices were produced and the respondent sought for explanation. The petitioners replied that the license under Form-10 was not mandatory at the time of procurement of the goods and they do not have Form-10 license, nor have they any stock of the goods. Thereafter, on 10.03.2011, the respondent issued show cause notice to the petitioners for importing Albendazole CP 2000, without obtaining license under Form-10 and contravening the provisions of Section 10(c) and 18(b) of the Act, 1940. On 09.04.2011 and 11.04.2011, the petitioners sent a reply to the respondent and the relevant portion is extracted hereunder:-

> "1.The Substance Albendazole is 2-Methoxy Carbonylamino-5-Propylthio-1H-Benzimidazole, and is used as precusser intermediate in the manufacture of

other chemical substances under the class of chemical Benzimidazoles Ex: fenbendazole etc. Therefore the albendazole intended for a use which is not medicinal use is exempted from the chapter of the Drugs and Cosmetics Act by vitue of provisions of the rule 43 read with Schedule D.

2.The substance Albendazole is widely used and recognized as n ingredient of the animal feed for maintenance of the health of animal including ruminants, avians, celine and equine origin (Fef: Merck Vet Manual). Therefore, the use of this substance is 'as part of animal food', and therefore not a Drug as 'used for as food' is not included in definition of the drug. Infact the definition has specially excluded the substance 'used as food'."

8.It is further submitted that the petitioners did not dispute the import of Albendazole CP 2000. The import was done through proper channel by producing all the relevant documents such as Commercial Invoice, Certificate of Analysis, Certificate of Origin, Bill of Ladding and Bill of Entry. The respondent, on misconception had proceeded that the imported substance is a drug within the meaning of Section 3(b) of the Act, 1940. No doubt Section 10(c) mandates a license for import of a drug, the consistent case of the petitioners is that the imported substance has been claimed and cleared as animal feed and imported as such and supplied to manufactures of animal feed to be used as supplements. Hence, the imported substance does not require license under Form-10.

9.The learned counsel for the petitioners further submitted that the claim of the respondent that the goods in question are listed in India Pharmacopoeia and the clarification received from the Department of Animal Husbandry, Dairying and Fisheries, Ministry of Agriculture and Farmer Welfare, Government of India, New Delhi. By Official Memorandum dated 25.10.2018 informed, Albendazole CP 2000 are not permitted for use in animal feed supplement, is on a wrong notion. The Ministry of Animal Husbandry has issued such communication only in the year 2018. Admittedly, in this case, the goods were imported and cleared on 05.06.2009 and the drums were labelled as 'not for medicinal use'.

10.In support of his contention, the learned counsel for the petitioners placed reliance on the order of this Court in the case of "S.Kesarimal Versus the Commissioner of Customs (imports), Chennai-I reported in 2010 (255) E.L.T 17 (Mad.)", wherein it was held that Form-10 is the import licence required to be obtained for import of drugs excluding those specified in Schedule X and Form 10-A is for import of drugs, specified in

Schedule X. Rule 40 speaks about the procedure for import of drugs. Rule 43 deals with import of drugs which do not require licensing. The said provision reads as follows:-

> "The drugs specified in Schedule D shall be exempt from the provisions of Chapter III of the Act and of the Rules made thereunder to the extent, and subject to the conditions specified in that Schedule. "

11.Further, held that Rule 123 under Part XI provides for exemption in respect of the drugs specified in Schedule K, which reads as follows:-

> "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."

12.Further, held that the substances imported are not intended for medical use, the importer shall certify that the substance is imported for non-medicinal uses. If the import is otherwise than in bulk, each container shall bear a label indicating that the substance is not intended for medicinal use or is intended for some purposes other than medicinal use. Further, when a particular drug is imported not for the purpose of use in the manufacture of a drug, but to be used in manufacture of food supplement, Rule 23 of the Act has no relevance in this case.

13.The learned counsel further submitted that the drug Albendazole CP 2000 intended for use which is non medicinal is exempted from Chapter III of the Act and by virtue of Rule 43 r/w Schedule D of the Drugs and Cosmetics Rule, 1945. For better appreciation Schedule D of the Drugs and Cosmetics Rule, 1945 is extracted hereunder:-

S.No.	Class of Drugs	Extent and conditions of exemption
1.	Substances not intended for medical use	All provisions of Chapter III of the Act and Rule thereunder subject to the condition that if the substance is imported in bulk, the importer shall certify that the substance is imported for non-medical uses, and if imported otherwise than in bulk, each container shall bear a label indicating that the substance is not intended for medicinal use or is intended for some purposes other than medicinal use or is of commercial quality.

14.Following the above case, the High Court of Delhi in the case of "Chemical Centre (India) Versus Commissioner of Customs reported in 2011 (264) E.L.T. 325 (Del.)", held that "if the imported are not for any medicinal purposes and also will not sell it to any party, who is likely to use the goods for medicinal purposes, they are not required to obtain license."

15.The learned counsel for the petitioner further submitted that the Hon'ble Division Bench of this Court in the case of "D.K.Enterprises Versus Commissioner of Customs (Imports) reported in 2012 (281) E.L.T. 391 (Mad.)" had endorsed the viscus of S.Kesarimal (cited supra) and held that the question of obtaining license does not arise when the goods imported are not for medicinal use.

16.Aggrieved over the order passed by this Court in the case of S.Kesarimal (cited supra), the Department had preferred Appeal before this Court. The Hon'ble Division Bench of this Court in W.A.No.1559 of 2010 by judgment dated 23.12.2012, dismissed the appeal, against which the department had preferred Special Leave Petition (Civil) No.1519 of 2013 before the Hon'ble Apex Court, which was also dismissed.

17.Further, the learned counsel for the petitioner placed reliance on the following cases, which followed S.Kesarimal case (cited supra):-

- M.S.Healthcare Private Limited Versus Commissioner of Customs (Imports), Mumbai reported in 2013(296) E.L.T. 375 (Tri.-Mumbai).

- M/s.Hingarh & Co. Versus the Commissioner of Customes and Ors. in W.P.(MD).No.16098 of 2012, dated 03.04.2014.

18.The learned counsel for the petitioners further submitted that the prosecution in this case, is time barred and hit by limitation. The punishment prescribed under Section 13(1)(b) of the Act, is only for 6 months with a fine of Rs.500/-. In such cases, Section 468(2)(b) will apply and the respondent ought to have filed the complaint within one year of the knowledge of the offence. In this case, the show cause notice was issued on 10.03.2011, on which date the respondent gained knowledge of the commission of offence is admitted. In view of the same, the prosecution ought to have been launched by March 2012. In this case, the complaint was lodged before the Court below on 12.07.2013 and the cognizance was taken on 15.12.2013. There is no petition for condonation and no order of the learned Magistrate condoning the delay before taking cognizance. Hence, taking cognizance of the offence beyond the period of limitation is bad in law.

19.In support of the above contention, the learned counsel for the petitioners relied upon the following citations:-

- R.Aghoramurthy Versus Bombay Dyeing reported in 1994 (31) ACC 79.
- State of Rajasthan Versus Sanjay Kumar and Others reported in (1998) 5 Supreme Court Cases 82.
- Ramesh Chandra Sinha and others Versus State of Bihar and others reported in (2003) 7 Supreme Court Cases 254.
- Zandu Pharmaceutical Works Limited and Others Versus Mohd.Sharaful Haque and another reported in (2005) 1 Supreme Court Cases 122.

20.Dr.D.Simon, learned Central Government Standing Counsel appearing for the respondent filed counter and typed set of papers and submitted that the drug viz., Albendazole CP 2000 was imported by the petitioner from China, without obtaining valid license under Section 10(c) of the Act. He further submitted that the drug was officially listed in Indian Pharmacopoeia and also listed in Schedule H of the Act. Further, a clarification was issued by the Assistant Commissioner (Trade) Department of Animal Husbandry, Dairying & Fisheries, Ministry of Agriculture & Farmer Welfare, Government of India, New Delhi by Official Memorandum dated 25.10.2018 that the drug Albendazole is not permitted for use in animal feed supplement.

21.The learned counsel for the respondent further submitted that the Albendazole CP 2000 is a drug as per Section 3(b) of the Act and it ought to have been imported only through license under Form-10. In this case, the petitioners imported 2000 kgs of Albendazole CP 2000 vide Bill of Entry No.223821, dated 26.05.2009 without license under Form-10. A conjoint reading of Rule 43 and Schedule D of the Act would indicate that any substance not intended for medicinal use is imported, the provisions of Chapter III of the Act and Rules thereunder would stand excluded and exempted. In the present case, the imported drug Albendazole was not for medicinal use, is without any material and substance.

22.The Commercial Invoice, Certification of Analysis, Certificate of Origin, Bill of Ladding and Bill of Entry produced by the petitioners. Nowhere, it is found that the drug Albendazole CP 2000 is not for medicinal use and it imported for the purpose of animal feed. He further submitted that in this case, the petitioner admitted that he has sold 300 kgs of Albendazole CP 2000 to M/s.Vidya Pharmaceutical Private Limited, Thane. The Drugs Inspector, CDSCO, West Zone, Mumbai conducted inspection and sent sample for testing/analysis to the Central

Drugs Laboratory, Government of India, Kolkata. The Central Drugs Laboratory, Government of India, Kolkata gave a report that the drug does not confirm to USP standards. Further submitted that the imported drugs having a dual purpose for use of raw materials in manufacturer of other drugs, requires an application to be made to CDSCO Headquarters, wherein a case to case examination would be undertaken, after due scrutiny permission to import dual purpose drugs would be granted. The petitioner in his reply dated 11.04.2011 to the show cause notice, admitted that the imported substance is used as a precusser intermediate in the form of other chemical substance under the class of chemical Benzimidazoles and also Albendazole CP 2000 is widely used and recognized as an ingredient of the animal feed. Thus, the petitioner admitted that the imported drugs having dual purpose.

23.The petitioners had sold Albendazole CP 2000 to the following pharmaceutical companies:-

Sold to	Qty (kg)	Invoice No.	Date
M/s.Medicamen Biotech Limited, Alwar, Rajasthan	700	CHEM452	26.09.2009
M/s.Rikenbik Pharma, Ambathur, Chennai	25	CHEM985	24.03.2010
M/s.Saar Biotech, Solan	50	CHEM918	10.03.2010
M/s.Saar Biotech, Solan	100	CHEM991	26.03.2010
M/s.Saar Biotech, Solan	100	CHEM115	15.05.2010
M/s.Saar Biotech, Solan	100	CHEM147	26.05.2020
M/s.D.M Pharma Solan	25	CHEM033	15.04.2010
M/s.Candor Biotech Ltd, Solan	25	CHEM170	01.06.2010
M/s.Arion Health Care, Solan	151	CHEM191	05.06.2010
M/s.Arion Health Care, Solan	50	CHEM233	15.06.2010

24.The drug Albendazole CP 2000 would not come under Schedule X and it is officially listed in the Indian Pharmacopoeia. The drug Albendazole CP 2000 was listed in schedule H drug and it has been used for anathematic (for medicinal use). Hence, the contention of the learned counsel for the petitioners that the imported substances would fall under Schedule D is not correct. The Deputy Drugs Controller, CDSCO, West Zone, Mumbai by communication dated 20.12.2010 informed the Deputy Drugs Controller CDSCO, South Zone, Chennai about the petitioners imported Albendazole CP 2000 and sold to M/s.Vidya Pharmaceutical Private Limited, Thane. Further, the samples were taken from M/s.Vidya Pharmaceutical Private Limited, Thane and sent to the Central Drugs Laboratory, Kolkata for test. From the report, it was found that the sample did not conform to USP with respect to the test for 'Chromatographic Purity'. On 22.12.2010 the officers of the South Zone CDSCO, Chennai visited the petitioners premise and conducted an investigation. During investigation, it was found that the 2000 kgs in 80 drums of Albendazole CP 2000 were imported by the petitioners from China without valid license and all the particulars were collected from the petitioners. The respondent issued show cause notice on 10.03.2011 to the petitioners that they have imported drugs without any license under Form-10 and contravened the provisions of Section 10(1) and 18(b) of the Act. On receipt of the same, the petitioners sent a reply on 11.04.2011 stating that Albendazole CP 2000 was imported by them is an animal feed and it is not a drug. The respondent sent a letter to the office of the Assistant Drugs Controller (I), CDSCO, Chennai Port on 21.04.2011, seeking details about the import of Albendazole CP 2000 by the petitioners.

25.The Assistant Drugs Controller (I), CDSCO, Chennai Port sent a communication dated 29.04.2011 to the Commissioner, Custom House, Chennai and sought clarification with regard to Bill of Entry in No.22382, dated 28.05.2009. The Commissioner, Customs House by communication dated 18.05.2011 informed that the petitioners import of Albendazole was assessed on 27.05.2009 and cleared on 05.06.2009.

26.Thus, it is clear that the petitioners without license under Form-10 had cleared the drugs and sold the same to various pharmaceutical companies, thereby violated the provisions of the Act and committed the offence. The respondent, after obtaining permission for prosecution and after nomination of law officer, lodged a complaint before the Court below on 12.07.2013. Due to the pendency of the above petition, the trial before the Court below could not be proceeded with. The points raised by the petitioners are factual in nature and to be decided during the trial and prayed for dismissal of the petition.

27.This Court considered the submissions made on either side and perused the materials available on record.

28.It is not in dispute that the petitioner imported 2000 kgs of Albendazole CP 2000 from China and the same was cleared by the Customs Department on 05.06.2009. It is also not in dispute that the petitioner had not obtained license under Form-10 before clearance of the goods. The contention of the petitioner is that the drug Albendazole CP 2000 substance was intended to be considered as ingredients of the animal feed and for non medicinal use. The petitioner produced the Commercial Invoice, Packing List, Certificate of Analysis, Certificate of Origin, Insurance Invoice, Bill of Ladding and Bill of Entry. In none of these documents, nowhere it is mentioned that the drug Albendazole CP 2000 is not intended for medicinal use. The stand of the petitioner that the drug Albendazole CP 2000 was for usage of supplement of animal feed is an after thought. The respondent in the counter had listed pharmaceutical companies to whom the petitioners had sold the Albendazole CP 2000.

29.The learned counsel for the petitioners placed heavy reliance on the case of S.Kesarimal (cited supra) and other citations, which had followed the same. In all the citations, the consignment were live consignment, wherein the Court had specifically given a direction to give undertaking that the imported substance are not to be used as drug and it is not for medical use. The facts of the cases cited by the learned counsel for the petitioners are not applicable to the facts of the present case. In this case, the consignment is a past consignment, already cleared by the Customs Department. The other citations relied by the learned counsel for the petitioners, is on the point of limitation.

30.It is admitted that in this case, the respondent conducted investigation on 22.12.2010 and issued show cause notice on 10.03.2011, seeking explanation for contravening the provisions of Section 10(c) and 18(b) of the Act. Thereafter, a reply was sent by the petitioners on 11.04.2011. Admittedly, the complaint was filed before the trial Court on 12.07.2013 and the complaint is for offence punishable under Section 13(1)(b) r/w 10(c) and 18(b) of the Act. The punishment prescribed under Section 13(1)(b) is imprisonment for a term which may extend to six months, or fine which may extend to Rs.500/-, or with both. As per Section 468(2)(b) of Cr.P.C., if the offence is punishable with imprisonment for a term not exceeding one year, no Court shall take cognizance of offence after expiry of period of limitation. In this case, the limitation period is one year as per Section 468(2)(b) of Cr.P.C. In this case, the investigation was conducted on 22.12.2010 and the show cause notice was issued on 10.03.2011.

31.Section 469 deals with commencement of the period of limitation and it reads thus:-

> "469. Commencement of the period of limitation - (1) The period of limitation, in relation to an offender, shall commence -
>
> (a) on the date of the offence; or
>
> (b) where the commission of the offence was not known to the person aggrieved by the offence or to any police officer, the first day on which such offence comes to the knowledge of such person or to any police officer, whichever is earlier; or
>
> (c) where it is not known by whom the offence was committed, the first the day on which the identity of the offender is known to the person aggrieved by the offence or to the police officer making investigation into the offence, whichever is earlier."
>
> A plain reading of the provision extracted above shows that in sub-section (1) three alternative starting points of limitation have been specified - (a) the date of the offence; (b) the first day on which an offence came to the knowledge of the person aggrieved by the offence or to any police officer, whichever is earlier, in a case where the commission of the offence was not known to any of them, or(c) the first day on which the identity of the offender is known to the person aggrieved by the offence or to the police officer making investigation into the offence, whichever is earlier.

32.In view of the above factual and legal position, the complaint ought to have been filed by the respondent by March 2012. In this case, admittedly, the complaint has been filed on 12.07.2013 and there is no petition for condonation of delay. Finally, the case was taken cognizance on 15.12.2013. The respondent contention that the complaint was earlier filed on 18.09.2012 was returned, questioning jurisdiction and finally, represented on 12.07.2013 and the trial Court took cognizance on 15.12.2013. Hence, the petitioners cannot be reason for the delay. In any case, the complaint has been filed after the period of limitation. Further, the petitioners had not filed any condonation of delay petition, the lower Court before taking cognizance of the offence, ought to have considered the delay and thereafter, on satisfying on the reasons given, condonation order to be passed. The lower Court before condoning the delay, notice ought to have been sent to the petitioners and heard. Admittedly, in this case, no such exercise has been done. In any case, the filing of the complaint by the respondent is beyond the period of limitation that is after March 2012, the cognizance taken by the learned XV Metropolitan Magistrate, George Town, Chennai on 15.12.2013, is clearly barred by limitation as per Section 468(2) Cr.P.C.

33.Thus, from the above, this Court finds that the continuation of the proceedings against the petitioners, is nothing but an abuse of process of law. Hence, the proceedings in C.C.No.43 of 2014, pending on the file of the XV Metropolitan Magistrate Court, George Town is, hereby, quashed. The petition is, accordingly, allowed. Consequently, the connected Criminal Miscellaneous Petition is closed.

s/d-
Assistant Registrar(CS-III)

True Copy

Sub-Assistant Registrar

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To

1.The XV Metropolitan Magistrate Court,
George Town, Chennai.

2.The Drugs Inspector,
Union of India,
Office of the Deputy Drugs Controller (India),
Central Drugs Stands Control Organization,
South Zone, 2nd Floor, Shastri Bhavan Annexe,
Chennai-600 006.

+1 Cc to Mr.B. Sathish Sundar, Advocate sr 33792.
+1 Cc to Mr.D. Simon Advocate sr 34063.

Crl.O.P.No.21289 of 2014

SAI(CO)
SP(21/10/2020)