IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED : 24.11.2020

CORAM

THE HONOURABLE Mrs. JUSTICE PUSHPA SATHYANARAYANA

W.P.No.1397 of 2020

M/s.Kawarlal & Co.,
No.27, Raghunayakulu Street,
Chennai-600 003
by its Proprietor K.Ramlal Jain .. Petitioner

Vs.

1. The Deputy Drugs Controller (India)
CDSCO, South Zone, Ministry of Health
and Family Welfare,
Government of India, 2nd Floor,
Shastri Bhavan Annexe,
No.26, Haddows Road,
Chennai-600 006.

2. The Drugs Inspector,
O/o.The Deputy Drugs Controller (I),
CDSCO, South Zone, Ministry of Health
and Family Welfare,
Government of India, 2nd Floor,
Shastri Bhavan Annexe,
No.26, Haddows Road,
Chennai-600 006.

3. The Asst./Deputy Commissioner of Customs,
(GR.2), Inland Container Depot (ICD),
Whitefield Plantations, Hoskete,
Customs House,
Bangalore-560 066. @

4. M/s.Nutranol Ingredients,
No.8/31, Ponnappa Chetty Street,
1st Street, Park Town,
Chennai-600 003, by its
Proprietor Sandeep Lalwani @ .. Respondents

@ R3 and R4 are impleaded vide order
dated 12.03.2020 in WMP No.7541
of 2020 in WP No.1397 of 2020

* * *

Prayer : Writ Petition filed under Article 226 of the Constitution of India praying for issuance of a Writ of Mandamus directing the respondents herein to consider the petitioner's representation dated 13.01.2020 seeking for a copy of the test report as directed to be issued by this Court in W.P.No.29302 of 2019 dated 10.10.2019 and for a further direction to release the locally procured goods, viz., Inositol NF 12 (Not for Medicinal Use) quantity of 35900 kgs, with Batch Nos.201812134 to 201812145, upon satisfaction of the test report, by also taking into consideration the shelf life of the goods and the further possibility of the deterioration of the goods, owing to its non-usage and further reduction in value of goods and the marketability of the goods.

* * *

For Petitioner : Mr.S.Baskaran

For Respondents: Ms.ME.Saraswathy for RR1 and 2

Mr.S.Rajasekar,
Senior Counsel for R3

Mr.M.Sachin Vijay for R4

O R D E R

The instant writ petition seems to be a continuation of an earlier order passed by this court on 10.10.2019 in W.P.No.29302 of 2019, which was also filed by the very same petitioner.

2. The petitioner, who is the proprietorship concern dealing in the business of importing and supplying of drugs and other raw materials required for the manufacture of chemicals, drugs, pharmaceuticals, food, neutraceutical, beverage industries, etc., has a valid licence under the Drugs and Cosmetics Act, 1940 (hereinafter referred to as "DC Act"), in Form 20B and Form 21B issued by the State Drug Control Authorities.

2.1. The petitioner had purchased 35,900 kilograms (kgs.) of Inositol NF 12 (Not for Medicinal Use) from the fourth respondent, which had admittedly imported the product from China vide Sales Invoice No.000342 dated 20.04.2019 for a valid consideration of Rs.1,20,73,170/-. After the purchase, the goods were reached the warehouse of the petitioner on 20.04.2019. The fourth respondent had imported the quantity of 36,000 kgs., from a manufacturer at China which were cleared from the Bangalore ICD Customs, after the customs officials have

properly assessed the Bill of Entry No.2693971, dated 03.04.2019 filed by the importer - the fourth respondent and thereafter, the major portion of the said imported goods was sold to the petitioner based on the purchase order.

2.2. The first and second respondents, during the course of the investigation/examination and inspection conducted at the warehouse of the petitioner concern, had issued Form 15 dated 25.04.2019 under Rule 54 and 145-C of the Drugs and Cosmetic Rules, 1945 (hereinafter referred to as "DC Rules") read with Section 22(1)(c) of the DC Act restraining the petitioner from anyway dealing with the said goods, i.e., the petitioner was restrained from selling, distributing and disposing of the said stock in their possession. Though the actual cause for such restriction was not known, it is stated that the petitioner was intimated that the respondents 1 and 2 had reason to believe that the said goods in the possession of the petitioner concern had contravened the provisions under the DC Act. Hence, Form 15 was issued, which has been periodically renewed till date.

2.3. The petitioner was also given to understand that the above goods, which were cleared from Bangalore Inland Container Depot (ICD), after having been properly assessed and cleared by the officers of the customs, but without a No Objection Certificate (NOC) given by Assistant Drugs Controller (ADC), Bengaluru, as the subject goods were cleared under the Customs Single Window System. Therefore, the petitioner approached their vendor - the fourth respondent, from whom the goods were purchased to sort out the legal complications involved in the matter, as the goods were purchased by them for a valid consideration and they have paid the entire amount.

2.4. In the meanwhile, the petitioner had also been approaching the Drug Control Authorities explaining the predicament and pleaded for release of the goods stating that if the said goods were not put to use, it would serve no purpose to anyone, since it has got a limited shelf life. The petitioner also had given a "Letter of Undertaking" dated 14.09.2019 at the request of the fourth respondent, since the fourth respondent had already applied for NOC from the Drug Authorities. It is stated further that the Drug Authorities had not come out with any proper response or explanation as to the reason for non-withdrawal or non-lifting of the restraint order, but only stated that the samples of the goods have been taken for testing.

2.5. As there was a huge delay in the goods being tested, the petitioner filed W.P.No.29302 of 2019 before this Court seeking for a Mandamus directing the respondent to test the goods, namely, Inositol NF 12 (Not for Medicinal Use) bearing (i)Sample No.LS/CS/SZ/2019/007; (ii) Sample No.LS/CS/SZ/2019/008

; and Sample No.LS/CS/SZ/2019/009 issued under Form 17, dated 01.10.2019 within a time-frame and also furnish a copy of the test report to the petitioner. This Court also had vide order dated 10.10.2019 directed the second respondent herein to test the said imported goods in any one of the accredited laboratory within a period of two weeks from date of receipt of a copy of the said order and furnish the copy of the report to the petitioner.

2.6. On 15.10.2019, the petitioner had attached the copy of the order passed by this Court and also gave an undertaking that the goods, which were locally purchased by them, would be sold/supplied only to the non-pharma industries, namely, food, neutraceutical, beverage, etc., and would not be sold to any pharmaceutical industries, while also giving an another undertaking that it would also produce the account details in respect of transaction held in respect of the sale of the subject goods made to such buyers and also would submit the periodic reconciliation data in respect of all such transactions carried out in respect of dealing/sale of the subject goods. One more reminder was also sent by the petitioner on 02.01.2020. The petitioner sent one another representation on 13.01.2020 seeking the copy of the test report and also release of the goods based on the test report.

2.7. The petitioner having purchased the goods locally for a valid consideration by making huge investment has filed this writ petition seeking for a direction for release of the goods, in view of the limited shelf life and also that any further delay would deteriorate the goods reducing the value and marketability of the material resulting in loss in their business.

3. A counter affidavit dated 03.02.2020 has been filed on behalf of the first and second respondents. The deponent of the same is one Dr.C.Saravanan, Drug Inspector. It is stated in the counter affidavit that 36,000 kgs. of Inositol NF 12 was imported through Chennai Sea Port and got cleared through Bengaluru ICD Whitefield Plantations, Bengaluru, without import licence in Form 10, as required under Section 10(c) of the DC Act. The purchase by the petitioner of 35,900 kgs. from the fourth respondent is also admitted. It is specifically pointed out that as per Section 43 of the DC Rules, if the imported drugs are not intended for medicinal use, the drugs specified in Schedule D shall be exempt from the provisions of Chapter III of the DC Act, subject to the conditions specified in that schedule. Point 1 of Schedule D specifically states that permission from licensing authority, as defined in clause (b) of Rule 21 has to be obtained for the import of the substance for non-medicinal use without registration and import licence. However, the fourth respondent had imported Inositol NF 12

without having No Objection Certificate, as required by Point No.1 of the above provision. It is also stated that the petitioner also had contravened the provisions of Section 18 of the DC Act, by purchasing it from the fourth respondent without Form 10/NOC from Licensing Authority. Even for the customs clearance, the fourth respondent ought to have submitted Form 10 or NOC from the Licensing Authority. Hence, there was a reason to believe that the petitioner had contravened the provisions of Section 18 of the DC Act, which resulted in issuance of Form 15.

3.1. It is also admitted that on 01.10.2019 three samples of Inositol NF 12 were drawn and sent to CDTL, Chennai, on the same day, in Form 18 for test and analysis. On 17.10.2019, the samples were returned to the Drug Inspector by CDTL, Chennai, stating the non-availability of facility to test the sample. The Drug Inspector had to request several Central Drug Laboratories regarding the facility to test the sample and the name of the laboratory is not disclosed for the sake of confidentiality. It is stated that the test report from the laboratory confirms that the material imported is Inositol NF 12 only.

3.2. An additional counter affidavit was also filed by the very same deponent on 19.02.2020, in which, it is stated that the first respondent had received a request dated 16.09.2019 from the fourth respondent on 17.09.2019 to issue NOC for the imported Inositol NF 12. The same was replied by the first respondent on 02.01.2020 vide reply Letter No.70-212/SZ/2019/3658 stating that Inositol NF 12 imported by the fourth respondent under Bill of Entry 2693971, dated 03.04.2019 has already been sold to M/s.Kawarlal & Co., Chennai-the petitioner herein and hence, NOC cannot be granted at that juncture. On 12.02.2020, the second respondent had also delivered one copy of all the three test reports to the petitioner and another copy to the fourth respondent.

3.3. There is yet another counter affidavit filed by the very same deponent on behalf of the first and second respondents on 21.08.2020 reiterating the very same averments.

4. The third respondent, who is the Assistant/Deputy Commissioner of Customs, Bengaluru, has also filed an affidavit in response to the petitioner's case. The said affidavit is filed by the Assistant Commissioner of Customs, who has stated that the subject goods Inositol NF 12 was imported vide Bill of Entry, dated 03.04.2019 and facilitated under Risk Management System (RMS), which is a self assessment scheme (CBIC Circular No.43/2005-Cus. dated 24.11.2005) for Accelerated Clearance for imports and exports under Accredited Clearance Program. It was recommended to introduce RMS as a measure of trade facilitation and for selective screening of Cargo through the Indian Customs EDI System (ICES). The system provides for special custom

clearance procedure for authorised persons (Accredited Clients) having good track record and who meets the specified criteria identified by the Customs. As the goods were cleared by auto clearance mode, it was not subjected to examination and passed out of the Customs Charge under the RMS mode and therefore, according to the third respondent, the goods were cleared only in a manner known to law.

5. The fourth respondent also had filed its counter affidavit explaining that the original import was made based on a Purchase Order placed by a Company in Bengaluru and as the same was cancelled, the goods were sold to the petitioner, who had also subsequently placed the Purchase Order. The goods were seized after they reached the premises of the petitioner. The NOC applied by the fourth respondent was rejected by the authorities, as the imported goods were also sold to third parties. It is also claimed that as the test report also certifies that the imported goods are only Inositol NF 12 and it is of standard quality, there cannot be any reason for withholding the same. Further, the petitioner also had given the undertaking to furnish about the particulars of the end users and considering the shelf life of the goods, the fourth respondent expressed no objection for release of the same in favour of the petitioner.

6. Heard the learned counsel on either side and perused the materials placed before this court.

7. The admitted facts by the petitioner as well as by all the respondents are that (i) Inositol NF 12 (Not for Medicinal Use) was imported in one consignment by the fourth respondent from the supplier/manufacturer at China, namely, Zhucheng Haotia Pharma Co. Ltd., vide Commercial Invoice No.INV19060, dated 27.02.2019 for a valid sale consideration of USD 133200 ; (ii) It was originally imported for a proposed purchaser M/s.Dolphin Chem International, Bengaluru, who had placed the Purchase Order dated 03.01.2019 ; (iii) as per the Purchase Order, the goods ought to have been delivered on or before 10.03.2019 ; (iv) As the goods were only arrived on 03.04.2019 and the same have been cleared from the Bangalore ICD customs on 19.04.2019, the Purchase Order was cancelled ; (v) Thereafter, the petitioner had also placed the Purchase Order vide Invoice dated 20.04.2019, referring the goods to be of non-medicinal use for a valid consideration of Rs.1,20,73,170/- and the goods were also delivered to the petitioner's warehouse on 20.04.2019 ; (vi) On 25.04.2019, Form 15 was issued for the reason that Form 10/NOC was not obtained by the fourth respondent.

8. Since an explanation has been given to both the importer - the respondent and the petitioner stating that the petitioner herein would use the imported goods for non-medicinal purposes

only, whether Rule 43 of the DC Rules would be attracted in this case has to be seen. 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."

A perusal of Schedule D at Sl.No.1 mentions that the "substance not intended for medicinal use" are exempt from all provisions of Chapter III and Rules thereunder, subject to the condition that if the substance is imported in bulk, the importer shall certify that the substance is imported for non-medicinal use, 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 other purposes other than medicinal use or is of commercial quality.

9. If the above rule read with Schedule D exempting the substance not intended for medical use are applied to the instant case, it is clear that the fourth respondent had imported the above quantity of Inositol NF 12 mentioning that it is "Not for Medicinal Use" from the Overseas supplier and their sale in favour of the petitioner also indicates that it was not intended for medicinal use. Thus, a reading of Rule 43 of the DC Rules along with Schedule D shows that where the substance is not intended for medicinal use, which was imported in bulk, the importer shall certify that the substance is imported for non-medicinal use.

10. In the counter affidavits of the respondents 1 and 2 as well as the third respondent nowhere the contention of the petitioner that Inositol NF 12 was imported by the petitioner only for the purpose of non-medicinal use by way of selling to other non-pharma industries, viz., food, neutraceutical, beverage, etc., was denied. Only if the imported substance is used for manufacturing of drugs, the importer requires a licence and a certificate for exemption is provided under the above rule. Rule 23 speaks about the import licence, which reads as follows :

> "An import licence in Form 10 shall be required for the import of any biological or other special product specified in Schedule C or C(1), excluding those specified in Sch.X, and an import licence in Form 10-A shall be required for the import of drugs specified in Schedule X."

Even a plain reading of the above rule makes it clear that the depending on the purpose of import and the usage, for which, the import is made, the DC Act prescribes the procedure either for getting a licence under Rule 23 or going for an exemption under

Rule 43. Therefore, when a particular substance is imported not for the purpose of use and manufacture of a drug, but to be used only in the process of food, neutraceutical, beverage, etc., Rule 23 of the DC Rules has got no relevance, as Rule 43 exempts such import.

11. The requirement of an import licence in Form 10-A assumes importance depending on the usage for which the imported item is intended for. In the instant case, after this Form 15 was issued to the petitioner, the fourth respondent also had applied to the Drug Authorities seeking Form 10-A exemption. However, the same was rejected as the fourth respondent had already parted with the imported goods or sold the goods to the petitioner, without mentioning whether the import of Inositol NF 12 is exempted or not. Besides, the petitioner also has given an undertaking after the report indicates that the goods, which were locally purchased by them, would be sold supplied/sold only to other non-pharma industries, namely, food, neutraceutical, beverage etc., while giving further undertaking that it would also produce the account details in respect of transaction held in respect of sale of the subject goods made to such buyers and also submit the Periodic Reconciliation Data in respect of all such transactions carried out in respect of dealing / sale of the subject goods. The undertaking, as indicated above, is recorded. In the said undertaking, the petitioner had accepted its willingness to furnish the end-user particulars, which would safeguard the interest of the respondents for the purpose of the DC Act.

12. Considering the fact that the even the test reports indicated that the samples of standard as defined under the DC Act and the Rules framed thereunder stating that the samples conform the USP and when the provisions and the rules of the DC Act and Rules provide for efficient protection in the matters of import, obtaining of Form 10-A in terms of Rule 23 need not be insisted upon.

13. The petitioner was constrained to move this Court even for getting the reports of the lab test conducted in this regard, as he was issued with Form 15. When the fourth respondent is entitled for import without a licence by reason of exemption granted under the Rules and the DC Act, the import being one for manufacture and use of non-medicinal substances, by way of retaining the same for the purpose of penalty on the ground that the import is not supported by licence under Form 10A is unsustainable. As the Customs Department also has dealt with the goods in the RMS Mode, the fourth respondent was free to sell the imported substance to the petitioner. The petitioner, who is the purchaser locally, is put to hardship because of the attitude of the respondents and the delay in the release of the goods caused loss to the petitioner. In the light

of the above circumstances, the plea of the respondents that the fourth respondent had imported Inositol NF 12 without Form 10A licence and consequently, retaining the goods in the premises of the petitioner, who is a subsequent purchaser, is patently erroneous cannot be accepted.

14. At this juncture, it is relevant to state that this Court in S.Kesarimal V. Commissioner of Customs (Imports), Chennai-I, 2010 (255) ELT 17 (Mad.), in a similar circumstances, held as follows :

> "16. It is hereby recorded that the petitioner has expressed its willingness to furnish end-user bond which would adequately safeguard the interest of the respondents apart from serving the purpose of the Drugs and Cosmetics Act. Considering the proceedings of the respondents dated 24th August, 2009, as disclosed in the typed set of papers filed by the third and fourth respondent, the fact that the import is not for the manufacture of the drugs but for use in the manufacture of food supplement, when the Rules themselves contemplate sufficient protection in matters of import of an item which is capable of multivarious uses, the insistence on obtaining Form 10-A in terms of Rule 23 does not appear to be a correct approach and the same is contrary to the Rule and the understanding of the respondents as disclosed in the letter dated 24th August, 2009 found in the typed set of papers filed by the third and fourth respondents. Thus, going by the Rules, which provide for exemption from going for licence in Form 10-A depending on the purport for which the import is made, it is difficult to accept the plea of the respondents solely on the basis of the earlier undertaking given by the petitioner or for that matter, the possibility of using the imported items contrary to the disclosed purpose. With the power of inspection available to check any possible abuse, the view of the respondents that the imported items is capable of being used in the manufacture of drug overlooks the very provisions of Rule 43 and 123 of the Rules. Consequently, so long as the disclosed purpose of import is for use in the manufacture of food supplement and hence, falls for consideration either under Rule 43 or 123 of the Rules, it is not open to the respondents to insist on the petitioner obtaining the licence in Form 10-A.
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> 17. In the background of Rule 43 of the Rules, when the petitioner is entitled to import Benfotiamine without a licence by reason of exemption granted under the Rules of the Drugs and Cosmetics Rules, the purpose of import being one for manufacturing food

supplement, the question of detention by way of confiscation or further proceeding for the purpose of penalty on the ground that the import is not supported by licence in Form 10-A, hence, does not arise.

18. ......

19. Normally, this Court would have accepted the plea of the respondents on the ground of availability of an alternative remedy and the need for filing the objection to the show cause notice. However, having regard to the plain meaning of Rule 43 and 123 of the Rules and the practice of the respondents as indicated in the letter dated 24th August, 2009 that Benfotiamine was allowed to be cleared with a stamping in every consignment that the import is not to be used in drugs, I have no hesitation in rejecting the objection of the respondents in granting the relief to the petitioner. The petitioner has also expressed its willingness to furnish end-user bond which would be in consonance with Rule 43 of the Rules.

20. Having regard to Schedule D read with Rule 43 of the Rules, I have no hesitation in accepting the plea of the petitioner that the consignments shall carry the stamping that the import is not for the purpose of use in the manufacture of drugs.

21. In the light of the above circumstances, I reject the plea of the respondents on the availability of alternative remedy as well as on the merits of the detention. Having regard to the view that I have taken and in the light of the willingness expressed to furnish end-user bond by the petitioner that the import is for the purpose of use in the manufacture of food supplement and hence, governed by Rule 43 read with 123 of the Drugs and Cosmetics Act, I have no hesitation in allowing the writ petition, thereby quashing the proceedings dated 22.2.2010. The petitioner is entitled to remove the goods imported without getting a licence in Form-10-A as provided under Rule 23 of the Act. Consequently, the Writ Petition stands allowed.

22. It is hereby made clear that if the authorities come across any material that the imported substance cleared as an exempted item is not for the declared purpose, it is always open to the respondents to proceed against the petitioner in accordance with law."

15. The appeal taken up against the said order of this Court by the Drug Authorities in W.A.No.1559 of 2010 also failed and a Division Bench of this Court vide order dated 23.02.2012 rejected all the contentions raised by them. Though the authorities filed SLP No.1519 of 2013, recording the fact that the goods have since been cleared, the said petition was dismissed on 01.12.2014.

16. A learned Single Judge of Delhi High Court in Chemical Centre (India) V. Commissioner of Customs, 2011 (264) ELT 325 (Del.) went to the extent of directing the authorities to undertake surprise checks at the premises of the purchasers, to whom, the petitioner therein sold the drugs. The following observations and directions were made in the said order :

> " ..... 15. As explained by the Madras High Court in S. Kesarimal the declaration by the importer of the use of the imported goods for non-medicinal purposes is determinative of whether Rule 43 would be attracted in a given case. In the present case, the Petitioner has repeatedly stated that it is prepared to furnish an affidavit stating that it will not use the CAM imported by it for medicinal purposes and further that it will not sell the CAM imported by it to any person who is likely to use it for medicinal purposes. It is not possible for the Respondent to insist on any other certification by the Petitioner beyond what is required by Rule 43 or Rule 123 DCR. The Petitioner cannot be expected to ensure that the retailer to whom the Petitioner sells the imported CAM does not in turn sell it to a person who might use it for medicinal purposes. It is for the Respondents to ensure enforcement of the law to prevent any violation.
>
> 16. This Court takes on record the statement made by the learned Senior counsel for the Petitioner, on instructions, that the Petitioner will furnish within one week an affidavit to the Respondents undertaking that the Petitioner will supply to the Respondents a complete list of the purchasers of the CAM imported by it under the consignments in question. It would be open to the Respondents to undertake a surprise check of the premises of the purchasers as disclosed by the Petitioner. If the Respondents find that such purchasers have sold the consignment to a manufacturer of drugs or a person who is likely to use such goods for medicinal purposes, the Respondents will proceed to take action in accordance with law.
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> 17. For the aforementioned reasons, this Court sets aside the order dated 30th July 2010 and the consequent observation dated 2nd August 2010 of the

Customs Department requiring the production by the Petitioner of an NOC from the DCGI. ..... It is directed that the Petitioner will be permitted by the Respondents to remove the goods in question, which have already been cleared, upon the Petitioner furnishing to the Respondents within one week an affidavit stating that:

(a) The Petitioner will not use the imported goods for any medicinal purposes and also will not sell it to any party, who is likely to use the goods for medicinal purposes; and

(b) The Petitioner will furnish to the Respondents the complete list of all the purchasers of the CAM imported by it under the consignments in question.

18. It is clarified that it would be open to the Respondents to undertake surprise checks at the premises of the purchasers as disclosed by the Petitioner and further proceed in accordance with law, if it is found that the imported CAM purchased from the Petitioner by such retailers is in turn sold to others who use it for medicinal purposes....."

17. If the case on hand is considered with the principles stated in the judgments rendered in Kesarimal and Chemical Centre (supra), it is amply clear that the petitioner is entitled for the relief sought for in this writ petition.

18. In the result, as the first limb of the prayer has already been complied with, the remaining part of the prayer sought for in this writ petition is ordered. The respondents 1 and 2 are directed to release the goods, which were locally procured by the petitioner, namely, Inositol NF 12 (Not for Medicinal Use), after obtaining necessary undertaking, as indicated above, within a period of two weeks from the date of receipt of a copy of this order. However, there shall be no order as to costs.

Sd/-
Assistant Registrar(CS)

//True Copy//

Sub Assistant Registrar

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To

1. The Deputy Drugs Controller (India),
CDSCO, South Zone, Ministry of Health
and Family Welfare,
Government of India, 2nd Floor,
Shastri Bhavan Annexe,
No.26, Haddows Road, Chennai-600 006.

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3. The Asst./Deputy Commissioner of Customs,
(GR.2), Inland Container Depot (ICD),
Whitefield Plantations, Hoskete,
Customs House,
Bangalore-560 066.

+1cc to Mr.R.Rajasekar, Advocate SR.NO.37668

+2cc to Mrs.MR.Sarashwathy, Advocate SR.NO.37731

+1cc to Mr.S.Baskaran Advocate SR.NO.37878

W.P.No.1397 of 2020

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SDR 15/12/2020