IN THE NATIONAL COMPANY LAW TRIBUNAL
COURT NO. 5, MUMBAI BENCH

M. A. 1406/2019

In

C.P. 197/I&B/NCLT/MAH/2018

Under Section 60(5)(c) of Insolvency & Bankruptcy Code, 2016

Corporation Bank

…….Applicant

In the matter of
ICICI Bank

.....Financial Creditor

vs.

Unimark Remedies Limited

……. Corporate Debtor

Order delivered on: 20.01.2020

Coram: Hon'ble Smt. Suchitra Kanuparthi, Member (Judicial)

For the Applicant: Ms. Rathina Maravarman, Advocate
For the Resolution Professional: Ms. M Swati Advocate
Mr. Nishit Dhuva Advocate
Mr. Rohan Agarwal Advocate
Ms. Pooja Mahajan Advocate
i/b MDP & Partners
For the Successful Resolution Applicant: Mr. Mustafa Doctor Advocate
Mr. Nachiket Yagnik
i/b DSK Legal
For the Assenting COC Members: Ms. Aditi Mittal Advocate
Mr. Suvaaankoor Das Advocate
For Omkara: Mr. Kunal Kanungo Advocate
For the Promotors of the Company: Ms. Khushboo Rohra Advocate
Mr. Sahil Mahajan Advocate
For the Omkara – Raj chemical: Mr. Amir Arsiwala Advocate

Per: Suchitra Kanuparthi, Member (Judicial)

MA 1406 of 2019

The present application is referred to me by an order of Hon'ble President, NCLT, Principal Bench, New Delhi vide order dated 4thNovember, 2019 to adjudicate on the brief issue whether fresh valuation can be ordered in view of the dissenting judgement.

The above M.A. was heard by Division Bench consisting of Hon'ble BhaskaraPantula Mohan, Member(J) and Hon'ble V. Nallasenapathy, Member (T). The hon'ble Judicial Member ordered a fresh valuation and whereas the hon'ble Technical Member dissented with the order of valuation.

Background:

1. This Application is filed by the Dissenting Financial Creditor aggrieved by the Approval of Resolution plan by the Committee of Creditors (COC) who failed to maximize the assets of the Corporate Debtor (CD) as there is a strark contrast in the value of assets (both tangible & intangible) shown in the balance sheet of the CD for the financial year 2017-18 and the valuations arrived at by the two Registered Valuers appointed by the Resolution Professional during the CIRP process.

2. The valuation of the Plant & Machinery being Rs.241.63 and Intangible assets being Rs.205.65 crores as on 31.03.2018, was reduced by Rs.200 crores under the head Plant & Machinery and value of Intangible assets was assigned as zero, as per the two Valuation Reports submitted by the Valuers.

3. The CIRP process of the CD spring into action on 03.04.2018, by order of Hon'ble Bench of NCLT. The Financial Creditors claimed Rs.1073 crores under the Resolution Process. The COC meeting

dated 26.12.2018 recorded the liquidation value of Rs.111 crores after deducting the CIPR cost of Rs.13 Lacs. The Resolution Plan of RA (Consisting of consortium of ARCIL, Shamrock and Intas) was approved by COC on 1.01.2019 and 72.25% majority voted in favor of the plan.

4. The 7% dissenting Applicant filed this application seeking the following prayers:

i. that it be declared that the Resolution Plan of the First RA (a consortium of Asset Recovery Company (India)Limited, Shamrock Pharmachemi Private Limited) which had been voted in favour of the COC members on 26.12.2018 is unlawful and is against the principles and tenets of the Bankruptcy Code;

ii. that in the alternative, the successful Resolution Applicant of ARCIL Consortium (First RA) be extended an opportunity to improve their plan value to match with the intrinsic value of the CD pertaining to the tangible and intangible assets;

iii. that in the event the successful Resolution Applicant of the ARCIL Consortium (First RA) fails to improve their offer, inter se bidding be ordered to be conducted between both the Resolution Applicants beingthe ARCIL Consortium (First RA) and the Omkara Consortium (Second RA);

iv. that in the event the resolution value is not improved by the Resolution Applicants either voluntarily or in inter se bidding to match the intrinsic value of the CD, the AA be pleased to appoint two valuers holding extensive knowledge and expertise in valuing the pharmaceutical companies, to value the tangible and intangible assets of the CD (within a time frame fixed by this Tribunal) and submit their valuation reports in sealed covers;

Objections of 7% Dissenting Financial Creditor (Applicant):

1. The Resolution plans failed to maximize the assets of the Corporate Debtor (hereinafter called 'CD') which would in turn balance the interest of all stakeholders viz the financial creditors, the operational creditors including employees, workman and stakeholders.

2. The liabilities of all creditors (interalia the workers admitted claim) has not been met in the Resolution Plan.

3. The Financial Creditors have suffered a huge haircut.

4. The Resolution Plan is for a meagre amount and is not based on any appropriate and fair price discovery mechanism. The total assets including the fixed assets of CD was valued at Rs.629.24 crores as per the audited balance sheet of the year 2017-18, whereas the entire plan value in both the Resolution plans is Rs.123 crores.

5. The Resolution plan of successful resolution applicant proposes that Rs.80 crores will be invested towards sale of 'Bavla' business undertaking of 'INTAS' as and by way of 'Slump sale' which is totally against the letter &spirit of IBC and the Vapi Unit is being offered Rs.60 crores. But infact, the Bavla unit as per the valuation report dated 02.01.2016 of Anmol Shikri Consultants Pvt. Ltd., was valued at Rs.486.86 crores (Bavla) and Rs.274(Vapi).

6. Both the plants at Vapi and Bavla are operative and since operating plant & machinery value cannot be so deteriorated by CIRP valuers. Only 6 plants in the International market for manufacturing Carbapenem exist worldwide and the unit of CD is one of them. Carbapenem is a complex technology and high growth product. There is no question of having such a low value for the plant & machinery and the Intangible assets could never have been valued at zero value.

7. One of the members of RA (being INTAS had expressed their intention to buy Bavla Unit for Rs.150 crores saddled with all statutory dues/debts/out standings and now the value ascribed for both units being Rs.80 crores.

8. The CD is a financially distressed company which has "going concern surplus' which has not been preserved at all as the business of the CD is not sold at the 'real intrinsic value' (Intrinsic value mean both tangible and Intangible assets). Under the pretext of resolution process, the assets of CD are attempted to be transferred for a much lower amount than 'market value of asset'.

9. The Resolution plan indirectly paves way for the wealth transfer to the particular class viz: Resolution Applicants at the cost of all other stake holders and creditors of CD.

10. There is no uniform parameter adopted for payment to Financial Creditor

11. Under the pretext of warning letters dated 12.08.2016 issued to CD by US food & Drug Administration (USFDA), the intangible asset of CD has been valued at zero. The CD has

been doing their regular business of manufacturing and exporting generic drugs even after receipt of warning letters. The turnover of the CD during the CIRP being Rs.80 Crores, hence it is an error apparent on the face of procedures adopted by CIRP valuers in arriving at nil value to the Intangible assets of the CD on the ground of receiving the USFDA warning letters.

12. The procedure adopted for valuing Pharmaceutical Companies is entirely different when compared with valuation of non-pharmaceutical companies. The CIRP Valuers failed to value the assets of CD (Both Tangible and intangible) as per international standards adopted for the Pharmaceutical Companies.

13. The comparative chart of Fixed Assets, major two assets i.e., Plant & Machinery and Soft IPR Assets are significantly undervalued to the tune of Rs.400 Crores as below:

S.NO.		AUDITED BALANCE SHEET (ACCOUNTS)			CIRP VALUATION BY DELTA VALUERS		CIRP VALUATION BY RNC		ANMOL SEKRI'S VALUATION (JAN.2016)	
		2015-16	2016-17	2017-18	Liquidation Value	Fair Market Value	Liquidation Value	Fair Market Value	Liquidation Value	Fair Market Value

1.	Plant and Machinery (Net)	282.91	258.74	234.57	17.17	38.85	34.68	49.54	435.45	529.01
2.	Soft IPR Assets (Net)	203.09	201.06	205.66	NIL	NIL	NIL	Was not asked to value		
	Total	486.00	459.80	440.43	17.17	38.85	34.68	49.54		
					Liquid Value (Avg.): 25.93 Crs. FMV (Avg.): 44.20 Crs.					

14. The extract of Minutes of meeting of COC dated 01.11.2018 wherein technical advise was sought regarding deterioration of value of ANDAS if the warning letters were not cleared. From COC minutes dated 19.10.2018 and 13.08.2018 state that members consented to make payment of USD 245600/- towards GDUFA fee to retain license for export to US & Europe for which license retained for export to 63 countries. Still the Intangible assets were not given any value.

15. There are several key factors for valuating pharmaceutical companies such as follows;
    a) Discounted cash flow
    b) Forward P/E Ratio
    c) Strategic Exit Factors
    d) Biosimilar v/s Generics
    e) Risk-Adjusted Net Present Value (NPV)

16. In a pharmaceutical company, if the Intangible assets are not valued, the entire valuation of the said pharmaceutical company will be drastically affected.

17. No proper explanation offered for the inordinate delay in submission of valuation reports of both CIRP valuers.

Submissions of Resolution Professional:

1. The RP is not supporting any particular applicant, nor does he have anything against any other party to CIRP and is contesting the present MA on a limited issue of the allegations leveled against the RP.

2. Despite the valuation reports being shared well in advance, no member of COC including the Applicant raised any query or concern regarding the valuation except the queries in respect of the goods under Bailor-bailee arrangement.

3. The applicant failed to share wisdom on valuation during the CIRP process.

4. Valuation was conducted in compliance with the Code and CIRP regulations.

No questions raised by COC Members on the valuation

Despite the valuation reports being shared well in advance, no member of the COC including the Corporation bank raised any query or concernregarding the valuation except the queries in respect of the goods under the bailor – bailee agreement (which

queries were addressed by the valuers). It may be added that COC members also had a meeting with the valuers to discuss the valuation and no valuation related concerns were shared by the Corporation bank with them.

Valuation was conducted in compliance with the Code and the CIRP Regulations

Hence, the duty of the RP under the Code is not to value the Company but to appoint the valuers for valuation of the company. To ensure that the valuers are independent, Regulation 27 provides that the valuer should not be related to the Corporate Debtor or the RP.

5. The Code further provides for Fair Liquidation value under Regulation 35 as follows:

"35. Fair value and Liquidation value.
(1) Fair value and liquidation value shall be determined in the following manner: -

(a) the two registered valuers appointed under regulation 27 shall submit to the resolution professional an estimate of the fair value and of the liquidation value computed in accordance with internationally accepted valuation standards, after physical verification of the inventory and fixed assets of the Corporate Debtor;

(b) if in the opinion of the resolution professional, the two estimates of a value are significantly different, he may appoint another registered valuer who shall submit an estimate of the value computed in the same manner; and

(c) the average of the two closest estimates of a value shall be considered the fair value or the liquidation value, as the case may be.

(2) after the receipt of resolution plans in accordance with the Code and these regulations, the resolution professional shall provide the fair value and the liquidation value to every member of the committee in electronic form…."

6. Hence the valuation exercise was undertaken by the registered valuers in accordance with internationally accepted valuation standard after physical verification of inventory and fixed assets of the CD. After receipt of the resolution plans, the RP has to provide the fair value and liquidation value to COC. If two estimates are significantly different, the RP can appoint another registered valuer so that the average of the two closest estimates can be considered as fair liquidation value.

7. The role of RP is limited to share the values with COC members. The valuers to be appointed shall be registered valuers and regulated by IBBI as notified by the Code.

8. The COC ratified the appointment of two Valuers. M/s Rakesh Narula & co. has conducted valuation in more than 100 companies and Delta valuers & appraisers LLP has conducted multiple Insolvency valuations.

   (a) There is no process specified in the CIRP Regulations on format and manner in which the valuation reports are to be received by the RP from the valuers. Before the 8th meeting of COC held on 19th October 2018, the valuers shared their reports in PDF form with the RP and this fact was duly intimated to the COC members during the 8th COC meeting held on 19th October, 2018.

(b) The resolution plans were received on 31st October, 2018 were opened in the COC meeting of 1 November, 2018 and hence, the fair value and the liquidation value was shared in electronic form with the COC members on 6 November 2018 after receiving confidentially undertakings from the members.

(c) For sake of completeness, and to give opportunity to COC members to review and raise concerns (if any) on the valuation, the RP informed the COC members on 6 November 2018 itself that the valuation reports are available for inspection at RP's office.

(d) Certain concerns were raised on the aspect of inclusion of certain goods (under a bailor- bailee arrangement) in the valuation report of (RNC?) and therefore, a meeting was organized on 29 October 2018 between lenders and the valuers in this respect. This issue was also discussed during the COC meeting on the 24thDecember 2018 and only once clarity was received on this aspect that signed report was issued by RNC;

(e) Soft copies of the valuation reports were also shared with the members on 4th December, 2018.

9. The figures in the balance sheet for the financial year 2018 did not provide for valuation of intangible assets. The valuers have conducted the valuation after physical verification of assets of the CD. The valuation of intangible assets for the purpose of the balance sheet is undertaken as per the accounting standard on the basis of costs and investment made by R&D and intangible assets and does not reflect the liquidation or fair value of these assets.

10. The Information Memorandum (IM) is prepared by RP on the basis of balance sheets and accounts.

11. Transaction audit report is submitted by the auditor who is entrusted the task of valuation of assets.

12. Valuation undertaken by Anmol Shikri in February 2016 refer to fair market value of assets of CD. He is not a registered valuer.

13. The valuation by ICICI Securities is not a valuation report but a presentation to attract investor for the Company.

14. Information available online regarding acquisitions in Pharma space can never be determint of what should be the liquidation value of the company in CIRP.

15. Valuation is not exact science and based on estimates and perception of experts who are in the business of valuation.

16. It is incorrect to dismiss the reports of registered valuers.

17. The rectification of warning letters required a capex around Rs.20 crores.

18. Only two Resolution Plans were received for CD. The liquidation value or fair value conducted by valuers was never revealed to the bidders (except Omkara ARC who was part of COC and had access to valuation reports.

19. The Minutes of COC dated 01.11.2018, 14.11.2018, 04.12.2018 & 24.12.2018 recorded the discussion of rationale of valuation, the bidders provided justification of providing a certain value to the CD based on their diligence and risk perception such as the market for

carbepenem becoming very challenging and price of carbepenem having fallen.

Submissions of Committee of Creditors (COC):

1. The COC is constituted under Sec.21 of the Code and comprises of all Financial creditors of CD. The COC is required to carry out decisions for working of CD through voting.

2. The most significant role of COC in Sec.30 in relation to voting on resolution under Sec30(2) requires COC to approve a plan by not less than 66% of voting share of financial creditors, after considering feasibility and viability.

3. COC is vested with the power to take decisions regarding the fate of a company undergoing CIRP on the rationale that is an economic legislation and creditors have the required knowledge and commercial wisdom.

4. This application is untenable and not maintainable and has to be dismissed. The Resolution plan as approved by COC is under consideration and approval before this Hon'ble Tribunal.

5. The scope of judicial intervention is restricted to the conditions mentioned under section 31 of the code, the code specifically empowers the financial creditors to make commercial decisions through their vote and such decisions are not ordinarily subject to judicial interference.

6. The Adjudicatory Authority is not empowered to grant such declaratory reliefs as sought by the Applicant. Sec. 60(5) (c) lays down that this Hon'ble Tribunal has jurisdiction over any question of

law in relation to the proceeding arising out of Insolvency resolution of CD.

7. COC has followed due process.

8. The Registered valuers provided reasoned reports.

9. COC does not have the technical knowledge and/expertise either to carry out a valuation process or to delve into methodologies and manner of valuation carried out.

10. CD is facing warning letters issued by USFDA.

11. The value of assets mentioned in the financial reports of a company mentions book value and whereas the value of the assets derived by the valuers under the code specifically requires for determination of fair value or liquidation value. Therefore, the main contention of the applicant that the valuations provided by the valuation reports are incorrect in view of the value assigned to them in the audited financial reports of CD in the preceding years.

12. The investment of CD into development of products and molecules have been classified as 'Intangible assets' under development which includes investment carried out towards ANDA and DMF approval. Therefore, it is not the value of the Intangible Asset which can be equated with the liquidation value. The COC had reviewed the valuation reports in their commercial wisdom.

13. The valuation is not exact science and the technical expertise cannot be challenged before the courts without strong evidence.

Submissions of Successful Resolution Applicant:

1. Jurisdiction of the Tribunal under Sec.30(6), the plan as approved by COC has to be placed before the Tribunal for approval under Section 31 of the Code.

2. It is within the four corners of Sec.31 that this Hon'ble Tribunal exercises jurisdiction in deciding whether to approve or reject the plan.

3. Valuation of CD is dependent on the potential commercial profit/cash flow that can be earned by commercializing the products manufactured in that unit. The end products manufactured by the CD has seen a decline in commercial potential over the last few years due to increasing competition in the market, thus affecting pricing and ability of players to take market share. Hence the potential return on capital invested for any incoming investor has consequently declined.

4. The regulatory action by the drug authorities from developed markets has led to substantial loss in value of companies. Such actions impact existing sales and impacts further approvals.

5. The CD has filed Abbreviated New Drug Application (ANDA) in 2013-14 and are still awaiting approval from USFDA.The commercial potential of these drugs is limited.

6. USFDA had undertaken inspection of Bavla & Vapi units in March 2014 and thereafter issued a warning letters in 28.09.2015, there was re-inspection in 2015, which failed due to non-compliance. Second warning letter was issued in 2016.

7. Vapi unit received warning letter on 12.08.2016 and upon re-inspection by USFDA in September 2017, non-compliance was confirmed. May 2018 Diligence team EIR dated May 2018 asserted that Vapi unit is unacceptable for supply to US markets.

8. The book value of CD has not recorded the impairment impact of the delays due to regulatory actions on manufacturing facilities and intangible assets of CD.

9. Intas value to buy Bavla unit for Rs150 crores was based on certain assumption which were to be verified during due diligence process namely:
    a) availability of regulatory submissions/ approvals and correspondence with relevant regulatory authorities in all countries to the extent they are relevant for commercializing the products;
    b) maintenance of valid and active ANDA, NDA and product registrations by Corporate Debtor as required;
    c) manufacturing unit
    d) its complaint with relevant regulatory requirements;
    e) Conduct of business in ordinary course up to and including the completion of the transaction (buy out of the Bavla Unit);
    f) Evaluation of pipeline of products;
    g) Completion of inspections of relevant manufacturing sites by Intas Technical and Management team as well as Good Manufacturing Practice("GMP") Audit of these facilities;
    h) Current trading information which should confirm year ending March 2018 expected results;
    i) Full disclosure details of all employee details related to individuals.

10. Pursuant to the expression of Interest under the current CIRP Process in the year 2018, a detailed commercial, legal technical, tax and real estate diligence ("Diligence") was undertaken. The brief findings of the technical team of *Intas are as follows;*

    (a) all research and Development and Analytical Development activities have stopped at the Bavla unit;

    (b) several quality control instruments, stability chambers are under breakdown condition;

    (c) currently all sites of the Corporate Debtor are under FDA's warning letter.

    (d) Cephalosporins and Non-cephalosporins API units are in total shutdown condition and the utilities are very old and in a non-operational condition.

    (e) Bavla Unit needs changes as committed to MHRA (Medicinesand Healthcare regulatory Agency- UK) like modifications in filling line to add Glove ports, interlocking of doors and extension of LAF (Class A) in 2-3 areas. This will require a period of 12 months to restart the facility for manufacturing as the required modification is to be completed and requalification of the area, water systems, calibration, media fill is required to be undertaken.

    (f) Formulation facility in the Bavla unit was designed and executed by Biopharmex, Israel based company as Turnkey project. Project of approximately INR 4-5 crores is pending, therefore, Biopharmexhas blocked passwords of Building Management system and Process equipment.

11. Further, during the Diligence, there were certain observations which were made pertaining to the operation, land, sales of the Bavla unit which are as follows;

    (a) Normalized Working capital is not available, and the operating

losses have to be funded by Intas to the tune of INR 25 crore,
till the unit becomes fully operational and self-sustaining;

(b) Additional capex of INR 30 crore was estimated by the Intas technical team to get the asset operational and able to supply to the regulated markets as pert GMP standards;

(c) Out of the total Bavla land:
- 10 % of the land has clear and marketable title;
-37 % of the land has agricultural status;
-53 % is under litigation and does not have a clear and marketable title.

(d) There are various Legal issues pertaining to non-compliance under the applicable laws;

(e) World Health Organization and Local FDA licenses have expired since April 2017;

(f) As mentioned hereinabove, ANDA Approval for the two carbapenem products has been pending since January 2015 and December 2014 respectively, as the warning letters are issued. Therefore, the technical team has estimated an additional investment of INR 30 crores as additional capex requirement to complete infrastructural modifications required and other tasks for obtaining the said approvals.

(g) The carbapenem sales of the business reduced from INR 58 crore in Financial Year, 2017 to INR 14.7 crore in Financial year, 2018 and hence the losses widened;

(h) The sales price realizations of key carbapenem product (viz Meropenem) in Europe (which is primary market) reduced by more than 40 % during this period, thus affecting the business case.

12. The applicant has made allegations against two valuation reports, but has not produced any independent valuation report by registered valuer to show that valuations made were incorrect in any way.

13. The Successful Resolution Applicant attended various negotiation meetings and revised/modified the resolution plan and improved their offer.

14. The plan of the Resolution Applicant was thus approved by the COC with process advisors after due evaluation and consideration.

15. Further, the said plan submitted by the Successful Resolution Applicant was commercially viable as:

(i) the Successful Resolution Applicant is investing capex and working capital and hence return of such investments would only be by operating the facility by reviving it.

(ii) The successful resolution Applicant has shared financial projections of 3 years to COC and Resolution Professional which justifies the cash flows and entire feasibility of the acquisition and this also covers the interest cost of ARCIL which is already taken into account.

(iii) In case of Shamrock and ARCIL, Shamrock has provided required security as well as given personal guarantee which speaks about the positive revival and turnaround of the Corporate Debtor and the unit.

(iv) Shamrock and Intas are already in the field of Pharmaceuticals and have experience and expertise to revive both the units.

(v) Business projection for the next 3 years is given in detail and sets out of projections for the ongoing products in concern their sales, volumes etc., based on which the projections have been made and arrived at. These projections are in line with the existing assets on 'as is' basis as well as the Capex that will be invested in the unit are in line with the previous track record of the Corporate Debtor when the Corporate Debtor was doing well and hence these projections are very much possible, realistic and conservative.

(vi) The successful Resolution Applicant plan ensures that the both units of the Corporate Debtor, i.e. Vapi and Bavla unit is

revived and the business is maintained. Further, the jobs of the employees/ workmen in Vapi unit shall continue and the consenting employees /workman of Bavla Unit shall be transferred to Intas without any break or interruption in service and the same is specified in the said plan.

17. The applicant never raised any grievance pertaining to valuation or slump sale of Bavla unit during the COC meetings.

18. Intas is acquiring Bavla unit and that CD will execute business transfer unit in favor of Intas(BTA). The execution of BTA is beneficial for the business of CD and in the interest of all employees. The interest of all employees/workman of Bavla unit. Intas being a leading Pharmaceutical Company will require to infuse Rs.50 crores as capital expenditure to revive Bavla Unit.

Submission of Unsuccessful Resolution Applicant (Consortium of Omkara ARC and Raj Chemicals)

1. Under the provisions of IBC, the adjudicating authority is empowered under section 61 to adjudicate upon the issues arising out of IBC.

2. NCLT exercises the dual role being a quasi-judicial Tribunal form to exercise jurisdiction in relation to proceeding under Companies Act, 2013 and the matters arising out of IBC.

3. The adjudicating authority under rule 11 of the NCLT Rules has inherent jurisdiction which as follows;

"Inherent powers – nothing in these rules shall be deemed to limit or otherwise affect the inherent powers of the Tribunal to make

such orders as may be necessary for meeting the ends of justice or to prevent abuse of the process of the Tribunal".

4. The issues relating to valuation of assets of the CD has been captured in the minutes of the meeting dated 19.10.2018, 29.10.2018, 01.11.2018, 04.12.2018, 24.12.2018, 26.12.2018.

5. There was a confusion as to when the final valuation reports were prepared. The minutes of the meeting of the COC held on 19.10.2018 record that the valuation report from Delta Valuers was final, yet the minutes of the meeting held on 24.12.2018 record that it was only a draft valuation report. However, within an hour they agreed to handover the draft valuation report as final report despite not having any documents as sought for.

6. On the onehand the valuation report attributes nil value to the intangible assets of the CD, however, on the other hand the COC infuse money into the CD to renew his licensee.

7. The adjudicating authority while approving the Resolution plan under section 36 and 31 of the I and BC would have to satisfy itself that the Valuation repot prepared by the approved valuers were done after following the procedures set out in I and BC and the regulation therein.

8. The adjudicating authority cannot question the commercial wisdom of COC while approving the plan but the adjudicating authority has to come to an independent conclusion that the Resolution plan is not in violation in provisions of the IBC.

9. It is the duty of adjudicating authority to exercise the judicial powers and discretionary powers vested in it to call for any information as if may require to satisfy itself that any particular resolution plan is compliant with the provisions of the IBC.

10. There exists enough material on record to suggest that there is some amount of confusion as to the valuation of intangible assets of the CD and it cannot be prejudicial to any person / entity / stake holders if adjudicating authority exercises its discretion and jurisdiction to call for an independent valuers report in a sealed cover.

Submissions of the Promoter:

1. The CD has two plants which are operative and the valuers have valued an entire Company's plant and machineries at Fair Market Value (Avg.) of Rs.44 crores and Liquidation Value (Avg.) of Rs.26 crores, which in the past valued by bank's (Joint Lender Form) appointed valuer consistently thrice (2013, 2015 and 2016) at Fair Market Value (Avg.) of Rs.536 crores and Liquidation Value (Avg.) of Rs.441 crores.

2. The present valuers may lack the expertise to value the Pharmaceutical plant for its tangible assets, technology approval, soft (IPR) assets etc.

3. The Carbapenem Sterile plant at Bavla is not used and the value has not deteriorated. This is one of one of the only six plants available in international market.

4. Intas has opted for Bavla unit which consist of five units namely;
   a. Cephalosporin API Manufacturing Unit,

b. Non- Cephalosporin API Manufacturing Unit,
c. R & D Centre Unit and
d. Carbapenem API Manufacturing unit,
e. Carbapenem Sterile Injection Formulation Manufacturing Unit.

Biopharmaxhave estimated value of Carbapenem Sterile Injection Formulation Manufacturing Unit at US $ 15 million (i.e., Rs. 105 crores), which is just one of the 5 units at Bavla, Ahmedabad, Gujarat.

So, there is no question of having such a low value even in the remotest possibility for an entire company's plant and machineries at Fair Market Value (Avg.) of Rs. 44 crores and Liquidation Value (Avg.) of Rs.26 crores.

5. The CD's assets have been subjected to the valuation process and thus arrived at a comparative chart of Fixed assets, plant and machinery and intangible assets.
6. The soft (IPR) assets of CD consist of;
   a. ANDA/FDF Approval- License to participate in formulation;
   b. DMF Approval- License to participate in API (Active Pharma Ingredients / Bulk Drug);
   c. Technologies to manufacture API/Bulk drugs/intermediates of bulk drugs;
   d. Customers Approvals to source API and / or formulation from CDs;
   e. Market Penetration-as each country has different regulations for approval;

   Each component of above Soft (IPR) assets has an independent significant value, which should be given weightage and valueby the valuer;

7. The warning letters issued by the USFD authority on 28.09.2015 and 12.08.2016 is in respect of US market and no other foreign market. The CD is allowed to sell its products in the US market and 13 ANDA applications shall be cleared post curing of warning letters at a minuscule cost of Rs.12-15 crores.

8. COC had appointed technical consultants Mr. Vijay L. Kriplani who advised them about the cost of curing.

9. In case of SDR process, E&Y External Consultant appointed by the banks' JLF (Joint Lenders' Forum) had mentioned Fair Value of Intangible Asset as Rs.106 crores in its SDR Discussion Documents (Refer page no. 9) prepared for the banks. Hereto annexed and marked Exhibit "D" is SDR Discussion Document prepared by E and Y in February, 2016.

The Valuation Evidence

Valuation Report and Methods

Valuation report submitted by two registered valuers appointed by the Resolution Professional;

Reports submitted by the Mr. Rakesh Narula and Company

Current Assets;

1. The valuer has based their opinion on the information as available in peroxisomal financials as on 31.03.2018 and other details as provided by the management. The working valuation is tabulated as follows;

Particulars	Amount as per financials as on	Fair Value (Rs.	Liquidation Value (Rs.)

	31st March, 2018		
A. Intangible Assets	20,576.22	NIL	NIL
B. Non-current Investment	4.75	16.61	16.61
C. Long- Term Loans and advances	8,803.21	NIL	NIL
D. Other non-current assets	1,268.71	NIL	NIL
E. Inventories	3,564.98	611	550
F. Trade receivables	2,688.65	701.34	588.06
G. Cash and bank balances	337.27	94.36	94.36
H. Short term loans and advances	385.51	NIL	NIL
Total	37,629.3	1423.31	1249.03

Details of intangible assets provided financials as on 31st March, 2018 are as under;

Sr. no.	Particulars	Amount as per financials as on 31st March, 2018 (Rs.)	Realizable Value (Rs.)
1.	Technical Know How	11.87	Nil
2.	Process Know How	1336.08	Nil

3.	Intangible Assets Under Development	19,228.27	Nil
Total		20,576.22	Nil

Reasons for valuation for intangible assets

It has been informed to us that intangible assets are mainly expenditure incurred on research and development on products to be sold in regulatory markets. Company has submitted 52 DMFs and 21 ANDAs with USFDA (regulatory authority in US). At present, USFDA has issued warning letter due to company's failure to comply fully with regulatory conditions. Also, ANDAs approval is on hold due to warning letter issued to the company. Since the warning letter is in public domain, it has adversely impacted exports to regulatory markets. Due to non-compliance of warning letter, USFDA can issue import alert at any time and in that case, export would be completely stopped and USGDA approvals to plant and products will be affected for next 4-5 years.

Further, pharma companies producing formulations are reluctant to refer to company's DMF's since the warning letter has been issued against the company by USFDA.

Based on above details provided to us, in our opinion fair and liquidation value of intangibles of the company is NIL.

Reports submitted by the Delta Valuers and Appraisers LLP

Basis /Method of Valuation

Intangible assets

Intangible assets	Fair Value (Rs)	Liquidation Value (Rs)
Intangible Assets	-	-
Intangible assets under		

Development	-	-
Total	-	-

The intangible assets comprise of Technical Knowhow and Process knowhow amounting to Rs13.47 crores and R&Dcosts for molecules as Intangible assets under development amounting to Rs.192.28 crores. However, the FV and LV have been considered as zero since the company has received a warning letter from USFDA authorities for its products and plants. The warning letter has kept approval of ANDAs on hold and has also adversely impacted the company's exports to regulatory markets. The USFDA authorities can issue IMPORT ALERT at any time due to noncompliance of WARNING LETTER. In such cases exports would stop instantly and USFDA approvals to plant and products will be affected for the next 3 to 4 years. In such a situation, it is not possible to make an assessment of commercial value of ANDAs / Intangible assets.

Question of law

1. Whether the adjudicating authority has the jurisdiction of judicial review and appoint an independent valuer to conduct fresh valuation of Intangible assets of CD?
2. Whether there is any error apparent on the face of valuation reports submitted by the two registered valuerscontrary to the accounted balance sheets of the CD for the year 2018?

1. Scope of Judicial Review

The scope of judicial review is drawn from Sec.30, Sec.31 read with Sec.60(5)(c) and the ratio laid down by Hon'ble Supreme Court in its recent judgement in Committee of Creditors of Essar Steel India Limited v. Satish Kumar Gupta & Ors. (2019 SCC Online SC 1478)

Section 30: Submission of resolution plan:

(6) The resolution professional shall submit the resolution plan as approved by the committee of creditors to the Adjudicating Authority."

Section 31 of the IBC as follows:

31. (1) If the Adjudicating Authority is satisfied that the resolution plan as approved by the committee of creditors under sub-section (4) of section 30 meets the requirements as referred to in sub-section (2) of section 30, it shall by order approve the resolution plan which shall be binding on the corporate debtor and its employees, members, 3[including the Central Government, any State Government or any local authority to whom a debt in respect of the payment of dues arising under any law for the time being in force, such as authorities to whom statutory dues are owed,] creditors, guarantors and other stakeholders involved in the resolution plan.

Section 60(5) of the I and BC as follows;

(5) Notwithstanding anything to the contrary contained in any other law for the time being in force, the National Company Law Tribunal shall have jurisdiction to entertain or dispose of—

a. any application or proceeding by or against the corporate debtor or corporate person;

b. any claim made by or against the corporate debtor or corporate person, including claims by or against any of its subsidiaries situated in India; and

c. any question of priorities or any question of law or facts, arising out of or in relation to the insolvency resolution or liquidation proceedings of the corporate debtor or corporate person under this Code.

1. Legal Principles and ratio cited in recent judgement of Hon'ble Supreme Court in

In Committee of Creditors of Essar Steel India Limited v. Satish Kumar Gupta & Ors. (2019 SCC Online SC 1478)

"Thus, it is clear that the limited judicial review available, which can in no circumstance trespass upon a business decision of the majority of the Committee of Creditors, has to be within the four corners of Section 30(2) of the Code, insofar as the Adjudicating Authority is concerned, and Section 32 read with Section 61(3) of the Code, insofar as the Appellate Tribunal is concerned, the parameters of such review having been clearly laid down in K. Sashidhar (supra). 43. However, Shri Sibal exhorted us to hold that K. Sashidhar (supra) missed a very vital provision of the Code which is contained in Section 60(5) of the Code. Section 60(5) reads as follows: "60. Adjudicating Authority for corporate persons xxx xxxxxx (5) Notwithstanding anything to the contrary contained in any other law for the time being in force, the National Company Law Tribunal shall have jurisdiction to entertain or dispose of— (a) any application or proceeding by or against the corporate debtor or corporate person; (b) any claim made by or against the corporate debtor or corporate person, including claims by or against any of its subsidiaries situated in India; and 68 (c) any question of priorities or any question of law or facts, arising out of or in relation to the insolvency resolution or liquidation proceedings of the corporate debtor or corporate person under this Code." It will be noticed that the non-obstante clause of Section 60(5) speaks of any other law for the time being in force, which obviously cannot include the provisions of the Code itself. Secondly, Section 60(5)(c) is in the nature of a residuary jurisdiction vested in the NCLT so that the NCLT may decide all questions of law or fact arising out of or in relation to insolvency resolution or liquidation under the Code. Such residual jurisdiction does not in any manner impact Section 30(2) of the Code which circumscribes the jurisdiction of the Adjudicating Authority when it comes to the

confirmation of a resolution plan, as has been mandated by Section 31(1) of the Code. A harmonious reading, therefore, of Section 31(1) and Section 60(5) of the Code would lead to the result that the residual jurisdiction of the NCLT under Section 60(5)(c) cannot, in any manner, whittle down Section 31(1) of the Code, by the investment of some discretionary or equity jurisdiction in the Adjudicating Authority outside Section 30(2) of the Code, when it comes to a resolution plan being adjudicated upon by the Adjudicating Authority. This argument also must needs be rejected."

"46. This is the reason why Regulation 38(1A) speaks of a resolution plan including a statement as to how it has dealt with the interests of all stakeholders, including operational creditors of the corporate debtor. Regulation 38(1) also states that the amount due to operational creditors under a resolution plan shall be given priority in payment over financial creditors. If nothing is to be paid to operational creditors, the minimum, being liquidation value - which in most cases 74 would amount to nil after secured creditors have been paid - would certainly not balance the interest of all stakeholders or maximise the value of assets of a corporate debtor if it becomes impossible to continue running its business as a going concern. Thus, it is clear that when the Committee of Creditors exercises its commercial wisdom to arrive at a business decision to revive the corporate debtor, it must necessarily take into account these key features of the Code before it arrives at a commercial decision to pay off the dues of financial and operational creditors. There is no doubt whatsoever that the ultimate discretion of what to pay and how much to pay each class or subclass of creditors is with the Committee of Creditors, but, the decision of such Committee must reflect the fact that it has taken into account maximising the value of the assets of the corporate debtor and the fact that it has adequately balanced the interests of all stakeholders including operational creditors. This being the case, judicial review of the Adjudicating Authority that the resolution plan as approved

by the Committee of Creditors has met the requirements referred to in Section 30(2) would include judicial review that is mentioned in Section 30(2)(e), as the provisions of the Code are also provisions of law for the time being in force. Thus, while the Adjudicating Authority cannot interfere on merits with the commercial decision taken by the Committee of Creditors, the limited judicial review available is to see 75 that the Committee of Creditors has taken into account the fact that the corporate debtor needs to keep going as a going concern during the insolvency resolution process; that it needs to maximise the value of its assets; and that the interests of all stakeholders including operational creditors has been taken care of. If the Adjudicating Authority finds, on a given set of facts, that the aforesaid parameters have not been kept in view, it may send a resolution plan back to the Committee of Creditors to re-submit such plan after satisfying the aforesaid parameters. The reasons given by the Committee of Creditors while approving a resolution plan may thus be looked at by the Adjudicating Authority only from this point of view, and once it is satisfied that the Committee of Creditors has paid attention to these key features, it must then pass the resolution plan, other things being equal."

Therefore, upon conjoint reading of Sec.30, Sec.31 with Sec 60(5)(c) of IBC and the ratio laid down in the judgement cited supra, I am of the opinion that the adjudicating authority has the jurisdiction of judicial review and appoint an independent valuer to conduct fresh valuation of Intangible assets of CD.

2. <u>Four essentials factors to be relied upon while considering whether the valuation of Intangible assets needs to be ordered:</u>

a. The balance sheet of the CD for the year 2017 and 2018. The accounted balance sheet for the CD for the year ending on

31.03.2017 and 31.03.2018 declared the intangible assets as follows;

	Notes	As at 31.03.2018 in Rs. (lakhs)	As at 31.03.2017 in Rs. (Lakhs)
Assets			
Non-current assets			
Tangible assets	11	32,536.09	35,548.74
Intangible assets	12	1,347.95	1,516.29
Intangible assets under development		19,218.55	18,589.41
Non-current Investments	13	4.75	558.47
Long term loans and advances	14	2,983.33	9,783.16
Other non-current assets	15	5.11	1,479.31
		56,095.79	67,475.38

b. This was the basis for valuation in the information memorandum, contrary to that the valuers as appointed by the Resolution Professional assigned nil value to the intangible assets on the sole premise that warning letters dated 28.09.2015 and 12.08.2016 were issued by the US FDA authorities can issue IMPORT ALERT at any time due to noncompliance of the same.

c. The applicant filed warning letters issued to CD and the warning letter contemplates as follows:

IN THIS SECTION: Warning Letters

WARNING LETTER

Unimark Remedies Ltd.

28/09/2015

Recipient:
Unimark Remedies Ltd
United States

Issuing Office:
Center for Drug Evaluation and Research
United States

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Silver Spring, MD 20993

Warning Letter

VIA UPS

WL: 320-15-17

September 28, 2015

Mr. Mehul J. Parekh
Managing Director
Unimark Remedies Ltd.
Enterprise Centre, 1st Floor
Off. Nehru Road
Vile Parle (E), Mumbai 400 099
India

FEI# 3005202703

Dear Mr. Parekh:

NOTARY
S. M. H. ZAIDI
Mumbai & Thane Dist.
Reg. No. 3640
GOVT. OF INDIA

During our March 18-21, 2014 inspection of your pharmaceutical manufacturing facility, Unimark Remedies Ltd., located at 337 Kerala Nalsarovar Road, Kerala Village, Savia, Ahmedabad District, India, an investigator from the U.S. Food and Drug Administration (FDA) identified significant deviations from current good manufacturing practice (CGMP) for the manufacture of active pharmaceutical ingredients (APIs).

These deviations cause your APIs to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B). The methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP.

We acknowledge receipt of your responses dated April 8, 2014, June 5, 2014, September 16, 2014, and November 28, 2014. We note that they lack sufficient corrective actions.

Our investigator observed specific CGMP deviations during the inspection, including, but not limited to, the following.

1. ***Failure to document production and analytical testing activities at the time they are performed.***

During our inspection, we found that test results and other entries in the production records were not entered while batches were in production. For example,

a. The investigator observed (b)(4) batch (b)(4) production on March 18, 2014. The start and stop times and (b)(4) for Step #(b)(4) were not recorded or signed in the batch record contemporaneously.

b. For your (b)(4) products returned due to the presence of extraneous threads, the investigator found many inconsistencies in your reprocessing batch records. Specifically, operators signed batch records for periods when they were not in your facility, indicating these activities were documented by personnel who did not perform them. During the inspection, and in your written responses, your managers admitted that the batch records were created after the manufacturing process.

c. Water testing records for sampling point (b)(4) on March 19, 2014, were incomplete. Specifically, the analyst did not record observations at the time they were made on March 18, 2014. Your microbiology records did not identify who prepared the samples, when they began incubation, who read the samples, or when the samples were read.

According to your responses to these FDA 483 observations, your manufacturing staff did not exhibit acceptable documentation practices, and your chemist or microbiologist each neglected his work. However, your management is responsible for routine oversight of manufacturing and testing operations, including the activities of operators and other personnel, and your responses do not address the failure of management and the flaws in your overall quality system.

In response to this letter, conduct and provide the results of a comprehensive investigation into your poor documentation practices. Your investigation should address the flaws in your quality systems and management oversight that led to these serious deficiencies. Provide your plans to revise your procedures so that all CGMP operations are documented at the time they occur. Also provide your plans to revise your procedures so that you preserve original or true copies of data in the batch records. Also provide your procedures for addressing deviations from acceptable documentation practices, including training and oversight of personnel whose duties require preparation and review of API records.

2. ***Failure to prevent unauthorized access or changes to data and to provide adequate controls to prevent omission of data.***

Your laboratory systems lacked access controls to prevent raw data from being deleted or altered. For example:

a. During the inspection, we noted that you had no unique usernames, passwords, or user access levels for analysts on multiple laboratory systems. All laboratory employees were granted full privileges to the computer systems. They could delete or alter chromatograms, methods, integration parameters, and data acquisition date and time stamps. You used data generated by these unprotected and uncontrolled systems to evaluate API quality.

b. Multiple instruments had no audit trail functions to record data changes.

We acknowledge your commitment to take corrective actions and preventive actions to ensure that your laboratory instruments and systems are fully compliant by January 15, 2015. In response to this letter, provide a copy of your system qualification to demonstrate that your electronic data systems prevent deletion and alteration of electronic data. Describe steps you will take (e.g., installing better systems or software) if your qualification efforts determine that the current system infrastructure does not assure adequate data integrity. Explain the

archival process your firm has implemented to address these issues and how you will evaluate the effectiveness of these corrections. Provide a detailed summary of the steps taken to train your personnel on the proper use of computerized systems.

3. *Failure to maintain complete data derived from all testing, and to ensure compliance with established specifications and standards.*

Because you discarded necessary chromatographic information such as integration parameters and injection sequences from test records, you relied on incomplete records to evaluate the quality of your APIs and to determine whether your APIs conformed with established specifications and standards. For example:

a. During the inspection, the investigator found no procedures for manual integration or review of electronic and printed analytical data for (b)(4) stability samples. Electronic integration parameters were not saved or recorded manually. When the next samples were analyzed, the previous parameters were overwritten during the subsequent analyses.

b. We found that some analytical testing data was inadequately maintained and reviewed.

i. Your HPLC 14 computer files included raw data for undocumented (b)(4) stability samples analyzed on December 30, 2013, but no indication of where these samples came from and why they were tested.

ii. In a data file folder created on May 22, 2013, 23 chromatograms were identified as stability samples for (b)(4) lots (b)(4), and (b)(4). Results were not documented. More importantly, the acquisition date was July 7, 2013, more than six weeks after the samples were run.

iii. (b)(4) lots (b)(4) and (b)(4) were not in your stability study records at the time of inspection. Additionally, there were no log notes of any samples from the three lots removed from the stability chamber.

You responded that "the probable reason for this inconsistency in data acquisition was due to some malfunction in the computer system at the time of data acquisition." Your response is inadequate because you have provided neither evidence to support this conclusion, nor a retrospective review of the effects your incomplete analytical data records may have had on your evaluation of API quality.

In response to this letter, provide your revised procedures and describe steps you have taken to retrain employees to ensure retention of complete electronic raw data for all laboratory instrumentation and equipment. Also, provide a detailed description of the responsibilities of your quality control laboratory management, and quality assurance unit for performing analytical data review and assuring integrity (including reconcilability) of all data generated by your laboratory.

4. *Failure to properly maintain buildings and facilities used in the manufacture of intermediates and APIs in a clean condition.*

We saw evidence of pests in your facility. For example, when we inspected your (b)(4) block, the (b)(4) manufacturing building was not sealed against pests. There were significant gaps in the (b)(4) level, where piping entered from outside. The investigator observed what appeared to be a bird's nest near the ceiling. On March 18, 2014, the investigator saw bird feces on a rack and on a bag of (b)(4) in the general raw material warehouse #2. On the same day, the investigator saw a lizard in the general raw material warehouse #1.

Your firm did not have written procedures for pest control. According to your responses, you performed corrective actions on the facility. However, you did not include any assessment of potential damage to your products.

Proper building design and maintenance, including operator training in prescribed cleaning and maintenance procedures are required elements of your facility's operations. In response to this letter, provide details of your pest prevention and control program and provide the results of your review of the effects of the presence of pests in your facility on API quality.

Summary

The examples in this letter are serious CGMP deviations. Your quality system does not adequately ensure the accuracy and integrity of data generated at your facility to support the safety, effectiveness, and quality of the drug products you manufacture.

We strongly recommend that you hire a qualified third-party auditor/consultant with experience in detecting data integrity problems to help you comply with CGMP requirements. However, it is your responsibility to ensure that any third-party audit evaluates your sophisticated electronic systems and their vulnerability to data integrity manipulation.

In response to this letter, provide

1. A complete evaluation of the extent of inaccuracies in your reported data. Include a detailed action plan to investigate the extent of your deficient documentation practices noted above.

2. A comprehensive investigation into root causes of the data integrity problems, including but not limited to independent interviews of current and former employees

3. A risk assessment of the effects of these deviations on data submitted in any pending drug applications.

4. A comprehensive management strategy to address these serious issues, including the details of your corrective action and preventive action plans.

   a) As part of your corrective action and preventive action plan, describe the comprehensive actions you have taken or will take to assure product quality. Contacting your customers, recalling product, conducting additional tests, adding lot numbers to your stability programs and monitoring complaints may be among the steps.

   b) Also include in your corrective action and preventive action plan, a section describing the actions you have taken or will take to prevent the recurrence of CGMP deviations, including breaches of data integrity. Revising procedures, implementing new systems and controls, and training or re-training personnel may be among the steps

The deviations cited in this letter are not intended to be an all-inclusive list of deviations that exist at your facility. You are responsible for determining the causes of the deviations identified above and for preventing their recurrence and the occurrence of other deviations.

If, as a result of receiving this letter or for other reasons, you are considering a decision that could reduce the number or volume of active pharmaceutical ingredients produced by your manufacturing facility, FDA requests that you contact CDER's Drug Shortages Staff immediately at drugshortages@fda.hhs.gov (mailto:drugshortages@fda.hhs.gov) so that we can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances in your drug manufacturing under 21 U.S.C. 356C(a)(1). FDA must consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the patients who depend on your products. In appropriate cases, you may be able to take corrective action without interrupting supply, or to shorten any interruption, thereby avoiding or limiting drug shortages.

Within 15 working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct and prevent the recurrence of deviations.

If you cannot complete corrective actions within 15 working days, state the reason for the delay and the date by which you will have completed the corrections. If you no longer manufacture or distribute the APIs at issue, provide the dates and reasons you ceased production. Please identify your response with FEI # 3005202703.

Send your reply to:

Xiaohui Shen
Consumer Safety Officer
c/o Division of Drug Quality
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research
White Oak, Building 51, RM 4223
10903 New Hampshire Ave
Silver Spring, MD 20993

Sincerely
/S/
Thomas Cosgrove, J D
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

NOTARY S. M. H. ZAIDI Mumbai & Thane Dist. Reg. No. 3640

Unimark Remedies Limited 8/12/16

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
10903 New Hampshire
Avenue
Silver Spring, MD 20993

Via UPS
16-27
Return Receipt Requested

Warning Letter 320-

August 12, 2016

Mr. Mehul J. Parekh
Managing Director
Unimark Remedies Ltd.
Enterprise Centre, 1st Floor
Off Nehru Road, Ville Parle E
Mumbai 400 099, India

Dear Mr. Parekh:

The U.S. Food and Drug Administration (FDA) inspected your manufacturing facilities: Vapi, Plot 41/42, Phase 1 – GIDC District Valsad Pardi, from May 18-22, 2015; and Belva, 300 Village Kerala, Bavla, Kerala Nalsarovar Road, Ahmedabad District, from August 3-14, 2015.

This warning letter summarizes significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drugs are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic (FD&C) Act, 21 U.S.C. 351(a)(2)(B).

We reviewed your firm's June 12, 2015, and August 30, 2015, responses (for Vapi and Bavla, respectively) in detail and acknowledge receipt of your subsequent correspondence.

Our investigators observed specific deviations including, but not limited to, the following.

Vapi Facility (FEI: 3004414652)

1. Failure to adequately investigate and document out-of-specification results and implement appropriate corrective actions.

Our investigator found that you failed to adequately investigate impurity specification failures for **(b)(4)** API batches #**(b)(4)** and #**(b)(4)**.

For example, for batch #**(b)(4)**, you concluded that the root cause of the failing impurity test results was an **(b)(4)** during manufacturing, even though your own records indicated that this batch was manufactured at the same **(b)(4)** as other batches that had passing results and were released. Similarly, for batch #**(b)(4)**, you attributed the failing test result to a **(b)(4)** step, even though your own investigation report lacked evidence to demonstrate that this was the assignable cause for the failure.

Your response acknowledges that your investigations into these and other out-of-specification (OOS) results are deficient, and indicates steps you have taken to improve your investigations. However, you have not provided a corrective action and preventive action plan (CAPA) that adequately resolves the specific OOS results discussed above, nor have you demonstrated how your broader investigation procedure improvements will address similar root cause analysis deficiencies in the future.

For more information about the proper handling of out-of-specification results and documentation of your investigations, please refer to *FDA Guidance for Industry: Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production* at http://www.fda.gov/downloads/Drugs/.../Guidances/ucm070287.pdf.

2. Failure to evaluate the potential effect that changes in the manufacturing process may have on the quality of your API.

Our inspection documented that you modified the manufacturing process multiple times for **(b)(4)** API. Your quality unit did not approve these changes, nor did you document themthrough a change control review process. Furthermore, you did not place samples from any of the batches produced through modified processes in your stability monitoring program to assess the effects of these changes on the quality of your API throughout the expiry period.

In your response you referenced stability data from batches not manufactured using the modified processes discussed above. Your response is inadequate because you do not have stability data to demonstrate that your API meets specifications throughout its expiry period.

Bavla Facility (FEI: 3008117347)

1. Failure to adequately investigate and document out-of-specification results and implement appropriate corrective actions.

Your firm routinely re-tested samples without documented justification and deleted analytical data. Our inspection found that you did not adequately investigate failing or atypical results. Although you obtained failing results in 2014, you did not initiate and document investigations for those failing results until July 2015. In addition, the conclusions of your investigations lacked supporting data.

Your firm's response attributed all unauthorized retesting of API batches to the lack of adequate training of your analysts.

2. Failure to ensure that test procedures are scientifically sound and appropriate to ensure that your API conform to established standards of quality and/or purity.

During the inspection, our investigator reviewed your growth promotion test procedures and on August 6, 2015, observed a growth promotion test failure of the **(b)(4)** tested on August 4, 2015. The test recovered *Pseudomonas aeruginosa* at **(b)(4)** percent, however, the acceptance criteria is **(b)(4)** to **(b)(4)** percent.

In your response, you indicated that the incubation times in your SOP for growth promotion tests were incorrect for **(b)(4)** and **(b)(4)** media. Your laboratory personnel, supervisors included, and your quality unit were not aware of this discrepancy. Your response fails to address the root cause of the growth promotion test failure.

3. Failure to maintain training records of employees involved in the manufacture of intermediates or API.

Our investigator found that your employees' CGMP training records contained numerous discrepancies that raise doubts regarding their authenticity. For example, the inspection documented that 10 of 11 training records contained identical handwritten responses. Our investigator also found incomplete training assessment forms for two employees. The forms indicated that the employees had not been evaluated as required in your procedures, yet the employees' training files stated that they had been evaluated as "very good" for the skills in question.

In response to this letter, provide a corrective action and preventive action plan to address your poor documentation practices and oversight of training activities. Include an updated training plan describing how you will ensure that all employees are adequately qualified to perform their assigned responsibilities in the manufacturing and laboratory operations.

4. Failure to properly keep buildings and facilities used in the manufacture of API in a clean condition.

Among other observations, our investigator found that the walls of your manufacturing area had open holes that could permit ingress of insects, birds, lizards, rodents, or other animals to the manufacturing space. During the inspection, the investigator observed dirt and birds in the manufacturing area as well as a lizard in the controlled (b)(4) processing area. Your response states that this area of your facility was (b)(4) and that the (b)(4) had (b)(4). Nonetheless, our investigators found a batch record inside this area demonstrating that you had been conducting manufacturing operations in this space as recently as August 2, 2015 — one day prior to the beginning of the inspection.

Conclusion

Deviations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these deviations, for determining the causes, for preventing their recurrence, and for preventing other deviations in all your facilities.

If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov, so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b) and allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

Until you correct all deviations completely and we confirm your compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug manufacturer. Failure to correct these deviations may also result in FDA refusing admission of articles manufactured at Unimark's Vapi and Balva facilities into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your deviations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov or mail your reply to:

Rafael Arroyo, Compliance Officer
Rebecca Parilla, Compliance Officer
U.S. Food and Drug Administration
White Oak Building 51, Room 4359
10903 New Hampshire Ave.
Silver Spring, MD 20993

d. Observations Regarding COC Minutes of Meetings:

1. *The minutes of the meeting of the COC dated 01.11.2018 have captured the following observations:*

   "The members of the COC enquired whether ANDA submitted with USFDA has been considered while submitting a Resolution plan to which Mr. Rikin Sanghvi, replied that the company has filed for ANDA and approval is awaited and company has also received warning letters from USFDA, resolving warning letter will take time hence the approval of ANDA will get delayed till the resolution of warning letter. Further, he enquired whether the valuers have taken the aforesaid criteria with respect to receiving of warning letter from USFDA into consideration while determine the Liquidation value of the company under the provisions of the Code. The members of the COC expressed their concerns with respect to the variable amount offered to them in the Resolution Plan. The Chairman acknowledged Mr. Rikin Sanghvi for addressing the COC and briefing them on the proposal made in the Resolution Plan submitted by them and requested them to leave the COC for further consideration".

2. *The members of the COC requested the Chairman to consult Mr. Vijay Kriplani, Technical Advisor of the Company as to whether non-clearance of warning letter so far had deteriorated the value of the ANDAs and the company so much. The chairman took note of the same.*

3. *COC meeting dated 04.12.2018, further observed that the valuation report has been received from the valuers. The COC members took note on the same and requested the chairman to share the reports with them.*

4. *The COC meeting on 24.12.2018 and 26.12.2018 has also discussed about the valuation update as follows: -*

   "the Chairman apprised the members of the COC that the Final Signed copy of the valuation report of Rakesh Narula and Co. has been received and soft copy of the same is circulated to the COC members. He added that the discussion on the value of the Current Assets in the valuation report of Delta Valuers is pending. Hence, he had called the representative of Delta Valuers to discuss in the meeting of COC.

   The Chairman invited and greeted Mr. Kushal Merchant, Mr. M B Brahmeya and Mr. Das representatives of Delta Valuers to discuss the valuation of the Current Asset specially the Bailor- Bailee transaction.

   Representatives from Delta Valuers were present at the meeting by invitation to put forth the issues before the COC for its inability to submit the signed valuation report. The chairman sought some clarification regarding some final valuation report with reference to bailor-bailee issue. After deliberate discussion the valuer agreed to provide the signed valuation report immediately.

   The minutes of meeting of COC post the submission of Valuation Reports did not deliberate on the issue of valuation of Intangible assets and thus the decision of Committee of Creditors needs to be re-considered.

Upon perusal of the warning letters supra, it can be said that warning letters contemplate corrective actions and state that the compliances with CGMP, FDA may withhold approval of any new applications or refusing admission of articles manufactured by CD at Bavla and Vapi units. No record has been placed that these bans were actually imposed and in the absence of the ban, the value of the Intangible

assets cannot be zero. The warning letters were only pertaining to drugs export to US and the CD has been exporting drugs to other countries worldwide. It is not the case that CD is exporting the drugs manufactured only to US. The reasoning of the two registered valuers in assigning a NIL value to the intangible assets of CD is absolutely untenable. The Valuation exercise was conducted on certain assumptions that warning letters negate the value of such assets. There was no reasoning provided by the Valuers whether these warning letters prescribe the risk factors and are subject to certain remedy or curative measure/precautionary steps envisaged to be carried out by the proposed Resolution applicant. The Valuers has not referred to any method of valuation in their report, no comparison was drawn of valuing the intangible assets of other Pharmaceutical Companies particularly in relation to the Domestic and International standard of valuation of such Intangible assets worldwide. A critical assessment of risk faced by warning letters ought to have been carried out in the light of available market expectation. Valuation is not exact science and court cannot disregard such report, unless there is a patent error. Therefore, it can be said that assigning nil value to Intangible assets is an error on the face of the two Valuation Reports and hence a fresh valuer needs to be appointed to the limited extent of providing a fair value of Intangible assets.

Conclusion:

The Counsel for the Applicant conceded that there is no element of fraud but only compares the value assigned to the intangible assets in the financial statement for the year 2017 & 2018 with the Information Memoranda and claims that this is an error apparent on the face of it. I conclude that the Warning letters issued by the USFDA is curable and entails the steps for compliance therein. Be that as it may, the reasoning of the Valuers for ascribing the *nil* value is absolutely

untenable in the interest of maximizing the assets of the CD. The value of Intangible assets of a going concern making profits even during CIRP cannot be stripped of under the premise of warning letters. No legal rights of any of the parties is affected if the exercise of fresh valuation is carried out, at best would assist the better valuation of CD as a going concern, though there were only two Resolution applicants willing infuse funds and revive the CD.

Though the valuers whose report is being questioned are not made parties to this application, I am entitled to look at the report and try to ascertain just what they are saying, in order to determine the extent to which they assist in the relevant debate.

In view of the judgement of Hon'ble Supreme Court in the case of COC of Essar Steel India Ltd v. Satish kumar Gupta & Ors (2019 SCC Online SC 1478), wherein it was held that discretion can be exercised to extend time to complete the CIRP process in exceptional cases and empowered to grant a relief, a fresh valuation exercise is ordered.

Therefore, it is ordered that the Resolution Professional take steps to appoint a fresh Valuer with a limited scope of valuing the Intangible asset considering the International standard of Valuation of a Pharmaceutical Company and submit his report within a period of two weeks of receipt of the order copy and the COC is directed to re-consider the valuation submitted by the third Valuer.
The Misc. Application is disposed off with the above direction.

Sd/-
Suchitra Kanuparthi
Member (Judicial)