(2013) 09 BOM CK 0020

In the Bombay High Court

Case No : Writ Petition (Lodg) No. 1714 of 2013

Johnson and Johnson Ltd. — APPELLANT

Vs

State of Maharashtra and Others — RESPONDENT

Date of Decision : 19-09-2013

Acts Referred:

Citation : (2013) 6 ABR 374 : (2014) 2 ALLMR 671 : (2014) 3 MhLj 428

Hon'ble Judges : S.J. Vazifdar, J;M.S. Sonak, J

Bench : Division Bench

Advocate : R.A. Dada, with Janak Dwarkadas, Ms. Gowree Gokhale and M.S. Ananth instructed by Nishith Desai Associates, for the Appellant; A.A. Kumbhakoni with Ms. Geeta Shastri, AGP and Ashutosh C. Gavnekar, Gurumurthy Iyer for Applicant/Intervenor in Chamber Summons., for the Respondent

Final Decision : Disposed Off

Judgement

S.J. Vazifdar, J.—Rule. Rule is made returnable forthwith and heard finally. The petitioner has challenged an order dated 30th March, 2013, passed by respondent No. 2-Joint Commissioner and Licensing Authority-Food and Drug Administration, cancelling the petitioner''s licence with effect from 24th June, 2013, and an order of the Hon''ble Minister dated 20th June, 2013, dismissing the petitioner''s appeal against the same. The result of the impugned orders is the cancellation of the petitioner''s licence in relation to Johnson & Johnson baby powder, a cosmetic powder with respect to it''s manufacturing facility situated at Mulund, Mumbai.

2. The petitioner is a part of the Johnson & Johnson group of companies which has been in existence for more than 127 years. The petitioner''s predecessor in title started its operations in India in 1947. In 1948, it started manufacturing the powder under the brand name and mark "Johnsons'' Baby Powder" (hereinafter referred to as "the powder"). The powder has been manufactured at the Mulund plant for over fifty years pursuant to and in accordance with the licences issued from time to time. The said licence bearing No. C/6 was issued to the petitioner

initially in March, 1965. The last renewal was on 13th March, 2013 which was after the issuance of the show-cause notice which we will shortly refer to and only 17 days'' before the impugned order dated 30th March, 2013 passed by respondent No. 2.

Prior to the impugned orders, the petitioner manufactured about 2000 batches of powder per month at the Mulund plant. There about 2000 employees at the plant.

3. The facts leading to the impugned order are as follows:

Fifteen batches of powder manufactured by the petitioner in the year 2007 required pH correction/re-processing as it was outside the mandatory specification range. If the pH factor is too low, the product becomes too acidic and if it is too high, it becomes alkaline. In either case, the product is said to be harmful to human skin and particularly to the skin of infants which is more delicate. The 15 batches of powder were bottled in 1,61,848 bottles. Before the same were despatched, even according to the respondents, the petitioner itself detected the high pH level and decided to re-process the entire produce to bring down the pH level within the permissible limits. Accordingly, all the bottles were emptied, the powder was collected in a processor and the same was treated by additional quantity of sesquicitrate . The pH level was, accordingly, corrected. The petitioner itself formed the opinion that it was possible that handling during the procedure may have increased the bio-burden (microbial contamination) outside the specified range. To ensure customer safety, it decided to treat the said 15 batches of powder with ethylene oxide. The process is referred to by the parties as ETO treatment. As the petitioner did not have an in-house ETO treatment facility, it decided to carry out the same at the licenced facility of a third party Microtrol Sterilisation Services Pvt. Ltd. The petitioner contends that the ETO treatment is not a part of the regular manufacturing process. It further contends that the Microtrol facility is licenced by the FDA for drug products. In the year 2007, Microtrol also used its facility for ETO treatment of other items such as spices, cosmetics and Ayurvedic drugs for which it was not required to have any FDA licence.

4. Microtrol, accordingly, treated the 15 batches of powder with ETO treatment. The powder was then brought back to the petitioner''s Mulund facility. According to the petitioner, it thereafter took all further steps required before selling the product, including testing each batch as per the mandatory monogram of skin powder for infants under Schedule S of the Act and the Rules, including Rule 142(c). Entries in that regard were made in the batch record sheet. It was only thereafter that the product was released for sale in compliance with the provisions of the Rules. The shelf life of the said 15 batches expired three years later i.e. in the year 2010. The present proceedings leading to the impugned orders commenced only three years later. It appears that the same was on account of the complaints/information received from a person whose name the respondents do not wish to disclose. The identity was disclosed by the person himself after we reserved this judgment. We will refer to his application for

intervention later.

5. By a letter dated 1st March, 2011, respondent No. 3-FDA-through the Commissioner requested the petitioner for information about the ETO process and the necessary safety data which was submitted at the time of approval certifying absence of residual ethylene oxide in the powder and justification for safety of the powder prepared by the process for its use on infants in India. The petitioner was called upon to submit the information within two days.

6. The petitioner, by its letter dated 2nd March, 2011, stated that it had initiated the data retrieval but requested for an additional 15 days time as the data requested pertained to the years 2006-2008. By a further letter dated 4th March, 2011, the petitioner furnished the information sought by respondent No. 3. The petitioner stated that its technical team would require some more time to retrieve the supporting data and other material. It stated that from the available consumer complaint data, it was found that the petitioner had not received any complaint in respect of the product and that the same indicated that the ETO treatment process under controlled conditions was safe. The petitioner submitted further information under cover of a letter dated 10th March, 2011, including the page numbers, the date of manufacture, the date of expiry, the date of the ETO treatment at Microtrol and the date of release of the products for sale.

7. The Joint Commissioner, FDA, visited the petitioner''s Mulund plant to carry out inspection with regard to the said 15 batches of powder. The petitioner recorded the same by a letter dated 24th February, 2012. By the said letter, the petitioner inter alia, stated that it tested three batches out of the said 15 batches for residual ethylene oxide in January, 2009 at PCP Chemicals Private Limited; that the basis of testing on three batches was limited amount of controlled samples that may be required for future reference; that the three batches covered different manufacturing dates and that the test reports confirmed the absence of ethylene oxide. The petitioner further stated that the final product was in conformity with the specifications viz. IS 5339:2004 skin powder for infants and as its claims related to the product remained unchanged, it did not approach the FDA in the matter. It is important to note that the petitioner also stated that all relevant information related to the incident was included as part of the corresponding batch manufacturing records. The petitioner confirmed that other than the said 15 batches, no batch had been treated with ethylene oxide.

8. Respondent No. 2 issued a notice dated 31st March, 2012, calling upon the petitioner to show-cause why the said licence No. C/6 dated 9th March, 1965, which was valid till 13th December, 2012, ought not to be cancelled. The show-cause notice stated that the petitioner had not taken permission from FDA for ETO sterilization process of the powder; that the petitioner had not informed the Licensing Authority after the ETO process; that if ETO sterilization process is followed, residual testing of ethylene oxide is required; that the petitioner had submitted the analysis report only of three batches and that in view of Section 18(3) of the Drugs and Cosmetics Act, 1940, the petitioner had violated the

conditions of the licence. The show-cause notice was issued in exercise of powers u/s 143(1) of the said Act.

9. The petitioner, by its letter dated 16th May, 2013, submitted a detailed reply to the show-cause notice. It is important to note certain contentions raised in this reply. The petitioner reiterated what was stated in the earlier correspondence. In addition thereto, the petitioner stated that the finished product, even after re-processing, conformed to the mandatory specifications and the product claims remained unchanged. The procedure was permissible GMP (good manufacturing practice) which was widely used across industries and is permissible under the said Act and the Rules framed thereunder. ETO treatment is a well known sterilisation process not only for pharmaceutical and surgical products, but also for several micro susceptible products such as absorbent cotton, food grains, plant extracts etc. The process at Microtrol is a validated process which involved evacuation of the chamber post ETO exposure followed by aeration to ensure absence of ETO residues. In view thereof, the petitioner did not test all the 15 batches post the ETO treatment. The three batches tested at the external laboratory also confirmed the absence of ethylene oxide residues. The petitioner opted for the ETO treatment as steam sterilisation was not a feasible option at the finished product stage.

10. As we mentioned earlier, the show-cause notice was dated 31st March, 2012. The petitioner replied to it by its letter dated 16th May, 2012. On 13th March, 2013, the FDA renewed the petitioner''s licence for a further period of five years.

11. The first impugned order was passed by the respondent No. 2 on 30th March, 2013. It is necessary to note the basis on which the impugned order was passed as the petitioner''s grievance is that before the Appellate Authority, contentions were raised by respondent No. 2, who appeared in the appeal to defend his order, which did not form part of the show-cause notice or of his order. The impugned order states as follows:

The petitioner did not obtain permission from the Licensing Authority to carry out the ETO treatment. The petitioner did not inform the Licensing Authority after carrying out the said treatment. If the ETO treatment is followed, residual testing of ethylene oxide is required. The petitioner submitted the analysis report of only three batches. As per the definition of the term "manufacture" in Section 3F re-processing a cosmetic product is a part of the manufacturing process. It was, therefore, essential for the petitioner to carry out residual testing of ethylene oxide before selling the same in the market. It was essential for the petitioner to test all the batches and not just three. The petitioner had, therefore, violated the provisions of the licence in view of Section 18(c) of the Drugs and Cosmetics Act, 1940. The failure to sell the powder without carrying out residual testing was serious. The order further stated as under:

This is very serious that the said licensee had sold the said batches sterilized with Ethylene Oxide treatment without carrying out residual testing. In this

respect, the said Licensee have mentioned in their explanation that as per IS 5339:2004" skin powder for infant-Specification does not require testing of Ethylene Oxide residual (Annexure B IV). This clarification is not satisfactory at all, as final phase of Sterilization for Skin Powder for infant does not applicable after carrying out Ethylene Oxide treatment by sterilization. Nevertheless, it has been mentioned in para 4.1.3 of specification that

The product shall not be manufactured from any carcinogenic ingredients. The said licensee has carried out final procedure without residual testing and using Ethylene Gas and sold all these batches in the market. If the Ethylene Oxide residue remains excessive in quantity, then there are possibilities of cancer to occur in future. Also the product is being used finally for infant, in my opinion, the health of many infants is put to risk by selling the product sterilized by using Ethylene Oxide treatment and without carrying out residual testing. Hence it has been proved that the complete precaution/care has not been taken before selling the product of Johnson''s Baby Powder in the market by the said licensee.

In view of the above, the said licensee have breached Drugs & Cosmetics Act & Rules made thereunder 1945, Rule 142(c).

During Personal Hearing, the said licensee has produced references of ISO 10150 ATSDR mentioning tolerance limit 50 ppm. It''s not correct to compare this specification with the powder which is being used on infant''s skin. Because infants skin is very delicate and manifestation cancer because of residual Ethylene Oxide. Hence this is very serious to keep continuing the business of the said licensee.

By the impugned order, the said licence was cancelled.

12. On 18th April, 2013, the petitioner filed an appeal before respondent No. 1. It is important to note that the petitioner, in paragraph 17 of the petition, expressly stated that it requested respondent No. 2 to allow it to carry out simulation exercise for ETO treatment process at Microtrol facility so that it could prove that the 15 batches were indeed safe. This was by a letter dated 11th June, 2013, which was produced at page 11 of a compilation tendered by Mr. Dada on behalf of the petitioner. Respondent No. 2, however, has to date not considered this application. The petitioner, therefore, performed the simulation exercise/experiment in an FDA approved laboratory Bee Pharmo Labs Private Limited for ethylene oxide residue. None of the samples showed the presence of detectable levels of ethylene oxide. According to the petitioner the test results of the simulation exercise demonstrate that by following the validated process, there is no possibility of any ethylene oxide residue in the product. The same was also stated by the petitioner in its appeal before the State Government. The petitioner''s appeal was dismissed by the impugned order dated 18th April, 2013, by the Hon''ble Minister, Food and Drug Administration.

13. The appellate order notes that the Joint Commissioner-respondent No. 2-appeared before the Appellate Authority and also notes his submissions. The

submission on behalf of respondent No. 2, as recorded in the appellate order, is that the licencee i.e. the petitioner did not obtain a loan licence to carry out the EO treatment and also did not inform the Licensing Authority after carrying out the treatment. The order also notes certain other contentions. It is necessary to set out the operative part of the order for, according to the petitioner, it contains no reasons. The relevant part of the operative part reads as under:

ORDER

After hearing from Dr. Bambulkar and Mr. Dinesh Singh, the representative of above mentioned applicant M/s. Johnson & Johnson Limited, Lal Bahadur Shastri Marg, Mulund (W), Mumbai-400 080 and Food & Drug Administration, Joint Commissioner (Greater Mumbai) and all concerned Commissioners, Greater Mumbai, I have found that Joint Commissioner (Greater Mumbai) & Licensing Authority, Food & Drug Administration, Mumbai have issued show-cause Notice dated 31 March, 2012 to the applicant, before issuing above mentioned order. Thereafter, after receiving explanation from the applicant dated 16 May, 2012, a chance was given during the personal hearing scheduled on 7 February, 2013 to the applicant to explain their views. In view of this it is very clear that a complete chance was given to the applicant to explain their views.

The applicant has agreed that they have reprocessed the 15 batches of Johnson''s Baby Powder by carrying out Ethylene Oxide Treatment at an external facility (M/s. Microtrol Sterilization Services Private Limited) and also they have not carry out residual testing for all the batches before selling into the market. Hence the organization have violated Drugs & Cosmetics Act, 1940, Section 18(c) and Rules made thereunder 1945, Rule 142(c).

In view of this, as per my authority of Drugs & Cosmetics Act & Rules thereunder of 1945, Rule 143(2), taking into consideration public health, hereby passing the following order:

1. Rejecting appeal of the applicant.

2. Accepting Joint Commissioner (General Mumbai) & Licensing Authority''s issued Order No. Parvane Radd/2429-12/Z-4 dated 30 March, 2013 to cancel the licence permanently effective 24 June, 2013.

Apart from holding that the petitioner was afforded an adequate opportunity by respondent No. 2, the Appellate Authority upheld the order of respondent No. 2 on two grounds viz. that the petitioner carried out the EO treatment at an external facility and had not carried out residual testing for all the batches before selling the powder. We presume that residual testing was a reference to the testing for ethylene oxide residue. The order does not appear to have been passed on the basis that the petitioner had not obtained a loan licence.

14. The petitioner''s further grievance in respect of the appellate order was that the appeal was heard on Thursday, 20th June, 2013 and that the order was passed at 7:00 p.m. the same day. 21st June, 2013, was a Friday and the order

was to come into effect from Monday, 24th June, 2013 and yet, the application for stay of the impugned order was refused.

15. Mr. Kumbhakoni, the learned counsel appearing on behalf of the respondents contended that after the ETO treatment, not even a sample of the product was tested by M/s. Microtol Sterilization Private Limited either at its processing unit or at the petitioner''s factory premises at Mulund or at any other laboratory for ascertaining whether there was any presence or absence of ETO residue. Mr. Kumbhakoni''s main contention, as is evident from the written submissions tendered by him, is that the ETO treatment of the powder constituted a manufacturing activity that could not have been conducted by the petitioner at Microtol''s unit without the petitioner obtaining a loan licence under Rule 138A read with Form 32-A of the Drugs & Cosmetics Rules, 1945. The petitioner having failed to obtain the loan licence, violated Section 18(c) of the Act. Sections 3F and 18(c) of the Act read as under:

3. Definition.--In this Act, unless there is anything repugnant in the subject or context,--

.....

(f) "manufacture" in relation to any drug (or cosmetic) includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug (or cosmetic) with a view to its (sale or distribution) but does not include the compounding or dispensing (of any drug, or the packing of any drug or cosmetic,) in the ordinary course of retain business; and "to manufacture" shall be construed accordingly;

18. Prohibition of manufacture and sale of certain drugs and cosmetics.--From such date as may be fixed by the State Government by notification in the Official Gazette in his behalf, no person shall himself or by any other person on his behalf--

.....

(c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under and in accordance with the conditions of, a licence issued for such purpose under this Chapter;

Rule 138-A reads as under:--

138-A. Application for loan licence to manufacture cosmetics.--(1) Application for grant or renewal of a loan licence for the manufacture for sale of cosmetics shall be made up to ten items of each category of cosmetics categorised in Schedule M-II in Form 31-A to the Licensing Authority and shall be accompanied by a licence fee of rupees two thousand and five hundred and an inspection fee of rupees one thousand for every inspection thereof.

Explanation.--For the purpose of this rule a ''loan licence'' means a licence which a Licensing Authority may issue to an applicant who does not have his own

arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by a licensee in Form 32.

(2) If a person applies for the renewal of a loan licence after its expiry but within six months of such expiry, the fee payable for the renewal of such a licence shall be rupees two thousand and five hundred plus an additional fee at the rate of rupees four hundred for each month or part thereof,

(3) The Licensing Authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture and facilities to undertake the manufacture on behalf of the applicant for a loan licence.

(4) The loan licence shall be granted by the Licensing Authority to only such applicants who propose to avail of the facilities of manufacture of cosmetics in the premises of a manufacturer located in the same State where the applicant is located. In case the manufacturer of cosmetics involves any special process of manufacture or use of equipments which are not available in the State where the applicant is located, the Licensing Authority after consulting the Licensing Authority where the manufacturing unit is located, may grant the loan licence.

(5) Subject to the provisions of sub-rule (2), application for manufacture of additional items on a loan licence shall be accompanied by a fee of rupees one hundred for each item subject to a maximum of rupees three thousand per application.

(6) A fee of rupees two hundred and fifty shall be paid for a duplicate copy of a licence issued under sub-rule (1) if the original is defaced, damaged or lost.

Rule 138-B stipulates that a loan licence to manufacture cosmetics for sale or distribution against application in Form 31-A shall be granted in Form 32-A. Form 32-A, in turn, requires the applicant to furnish various particulars about itself, including details of its licence. Clause 34 thereof stipulates that the licence, which obviously refers to loan licence, is subject to conditions stated below and to such other conditions as are specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940. The conditions of licence mentioned in Form 32-A do not specifically entitle the Licensing Authority to stipulate any other conditions. One of the issues that would have to be considered is whether additional conditions can be imposed or not. This would be an important aspect of this matter.

16. Mr. Kumbhakoni further submitted that the product after being treated was brought back to the petitioner''s factory and re-packed in 1,61,484 bottles and thereafter sold in the market. Before selling the product, the petitioner did not test the product to find out the presence or absence of ethylene oxide residue as required by Rule 142(c) which reads as under:--

142. Conditions of licence in Form 32-A.--

.....

(c) The licensee shall keep records of the details of each batch of cosmetic manufactured by him and of raw materials used therein as per particulars specified in Schedule U(I) and such records shall be retained for a period of three years.

It was only on 30th January, 2009, that the petitioner for the first time tested the samples. Moreover, this test was only in respect of three controlled samples. Further still, the test was conducted at M/s. PCP Chemicals Private Limited, Thane, which is not an institution approved by the Licensing Authority for conducting such tests as required under Rule 139(5)(ii), which reads as under:--

139. Condition for the grant or renewal of a licence in Form 32.--Before a licence in Form 32 is granted or renewed, the following conditions shall be complied with by the applicant:--

.....

(5) The applicant shall either-

.....

(ii) "make arrangements with some institution approved by the Licensing Authority under Part XVI(A) of these Rules for such tests to be regularly carried out in this behalf by the institution.

17. We agree with Mr. Dada''s submission that this aspect of the matter was not raised either in the show-cause notice or by respondent No. 2 while passing the impugned order dated 30th March, 2013. Further, the issue of loan licence was raised by respondent No. 2 only before the Appellate Authority. The contention is noted in the order of the Appellate Authority. However, the operative part of the appellate order does not indicate that it was passed on the basis or ground of the petitioner having failed to obtain a loan licence. Mr. Dada would be justified in contending that this contention is, therefore, not open to the respondents who must seek to sustain the impugned orders only on the basis of what is stated in the show-cause notice and in the impugned orders and not on any other ground. In other words, it is not open to the respondents to obtain orders on the ground that the petitioner had failed to obtain a loan licence. Indeed, absent Mr. Kumbhakoni''s submission based on the loan licence, it is difficult to ascertain any other provision that compelled the petitioner to carry out the test to ascertain whether there was any ethylene oxide residue after the powder was treated by Microtrol. Mr. Kumbhakoni submitted that the issue of loan licence was raised by respondent No. 2 before the Appellate Authority as is evident from the impugned order dated 20th June, 2013, which refers to respondent No. 2 having raised the issue. However, the Appellate Authority merely noted the argument. The operative part of the order and the reasoning do not deal with the issue. In any event, it does not deal with the issue satisfactorily. This is apart from Mr. Dada''s contention that this submission only finds place in the impugned order.

However, even assuming Mr. Dada is right, it is an issue which requires consideration and we are not inclined to merely set aside the impugned orders.

18. Mr. Kumbhakoni''s submission regarding the petitioner having failed to obtain a loan licence, however, requires serious consideration. This issue is of importance not only for this matter. It is of general importance as well. We are of the view that the issue as to whether the petitioner ought to have obtained the loan licence or not ought to be considered by the authorities in the first instance. On such an important aspect under the said Act we are not inclined to quash the impugned orders simpliciter on the ground that the respondents failed to observe the principles of natural justice. In our opinion it would be appropriate in such cases to not merely set aside the impugned orders, but to set them aside and remand them for fresh consideration after affording the petitioner an opportunity of being heard.

19. There is another important aspect of the petitioner''s case. The order cancelling the licence, albeit only with respect to the Mulund factory, prima facie, appears to be harsh in the facts and circumstances of this case. Neither of the impugned orders considers the doctrine of proportionality. They do not consider any of the relevant aspects in this regard. We will indicate only a few.

20. Firstly, even assuming that the petitioner was bound to obtain a loan licence and that it had failed to do so, there is nothing to indicate any mala fides on its part. Mr. Kumbhakoni also fairly did not attribute any mala fides on the petitioner''s part. He, however, raised a serious grievance regarding the petitioner''s refusal to admit its mistake. The petitioner''s licence has been in existence from the year 1965 i.e. for about fifty years. It''s manufacturing unit which has been ordered to be closed down, albeit qua only the manufacture of the said powder has about 2000 employees. The said 15 batches are the only batches in respect whereof the said treatment was done. The records in respect thereof were maintained. Samples were preserved. There are no allegations of tampering of the record by the petitioner. In fact, the impugned action is based only on the petitioner''s record. The petitioner itself carried out the tests in respect thereof as part of an internal audit although there was no obligation for it do so three years later. There is nothing on record that indicates that the said 15 batches in fact contained any defects of any nature whatsoever, including any ethylene oxide residue. The tests carried out by and at the instance of the petitioner indicate that the powder did not contain any harmful residue. To establish it''s bona fides, the petitioner has gone a step further. It has been ready and willing at all times for tests to be conducted not merely in respect of the samples of the said batches but also in respect of fresh batches of powder with the same treatment. It made the offer to the authorities as noted by us earlier. For some inexplicable reason, the authorities have not carried out the tests. As far as the petitioner is concerned, however, it is not merely a question of law that would arise on the issue of whether a loan licence was required or not. The authorities would also have to consider the bona fides of the petitioner especially

taking into consideration all the relevant facts indicated above or even otherwise while considering the issue of proportionality.

Mr. Dada, the learned senior counsel appearing on behalf of the petitioner placed considerable reliance upon two letters in this regard. The first is a letter dated 6th September, 2002, addressed by Microtrol to the Joint Commissioner at FDA enclosing correspondence with the FDA and other firms and stated that the same makes it clear that the activity of reduction of bio-burden does not require licence in Forms 25, 25D and 31. The second is a letter dated 30th September, 2002, addressed by the Joint Commissioner, FDA in reply to Microtrol''s letter dated 6th September, 2002. The letter reads as under:

With reference to your letter, we inform you that, as you do not certify or claim for'' "Sterilization" and other activities which are carried out for reduction of bio-burden for ayurvedic drugs and drugs other than those specified in Schedules C and C(1), therefore, as per aforesaid Act, you do not require license under Form 25, 25D and 31.

You are hereby instructed to take care of other deficiencies in future, which were found during the inspection.

21. Mr. Dada''s reliance upon the judgment of the Supreme Court in Om Kumar and Others Vs. Union of India, is well founded. The Supreme Court itself has held, however, that it is necessary for the authorities in the first instance to consider the quantum of punishment/penalty even assuming that the petitioner was guilty of any lapses.

22. The question then remains whether the impugned order ought to remain in force till the matter is decided on remand. In our view it is not necessary to do so for more than one reason.

23. Firstly, the alleged incorrect procedure was adopted only in respect of the said 15 batches. That procedure has not been applied thereafter. In any event, the petitioner states that it will not be applied hereafter. The statement is accepted. Secondly, the product continues to be manufactured at other units. Revoking the licence to manufacture the powder at the Mulund unit would not serve any purpose whatsoever except by way of a penalty. The question of the quantum of penalty is yet to be determined after the matter is decided afresh upon remand. There are 2000 workers at the Mulund unit. A major part of the activities at the Mulund unit pertain to the manufacture of the said powder. As on date, no complaints have been received. The absence of mala fides already indicated above is another factor in this regard.

24. We must mention the application by one Dr. Ajit Telang (hereinafter referred to for convenience as "the intervenor"). This writ petition was filed on 12th July, 2013 and was heard. The arguments were concluded on 2nd August, 2013 and we reserved our judgment. On 16th August, 2013, the intervenor mentioned the matter before us without notice to the petitioner. He requested us not to deliver

the judgment stating that he had information against the petitioner and wished to place the same before us. We informed him that he must follow the procedure if he wanted to make any application in any matter, including giving notice to the parties. Thereafter, we informed the advocates of the parties regarding the said application during the course of the day or probably the next day. Considering the nature of the matter, we did not pronounce the judgment immediately thereafter. On 16th August, 2013, the intervenor again mentioned the matter stating that he intended taking out a Chamber Summons for intervention. This application was made without notice to the parties. Subsequently, he sought circulation of the Chamber Summons before another Division Bench to which one of us (S.J. Vazifdar, J.) was a party, which granted him the circulation. On 13th September, 2013, the intervenor again, without notice to the parties, mentioned the matter before another Division Bench to which one of us (S.J. Vazifdar, J.) was a party. He was directed to make the application after notice to the other parties.

On one of the occasions, the intervenor stated that he had, in fact, approached the Appellate Authority and made his submissions before the Appellate Authority because of which the impugned order was passed. This hearing was in the absence of the petitioner.

By an order dated 16th September, 2013 in the intervener''s Chambers Summons (Lodg.) No. 240 of 2013, the other Division Bench passed an order stating that it would be more convenient for the same Bench to hear the Chamber Summons. Accordingly, pursuant to the order of the learned Chief Justice, the Chamber Summons was placed before us.

25. There are several serious allegations made by the intervenor against the petitioner regarding the procedure adopted by the petitioner which is the subject matter of the impugned orders. Considering the order that we intend passing, it is not necessary to entertain the intervention application. The intervenor is always at liberty to apply to the authorities hearing the matter on remand, to be heard. The authorities are at liberty to consider such application after affording the petitioner an opportunity of being heard even regarding such an application. It is not for this Court to consider the various technical aspects raised by the intervenor.

26. There are several serious allegations against the intervenor himself. For instance, the petitioner alleges that the intervention application is mala fide and only in view of the disputes between the petitioner and intervenor regarding his employment which was terminated by the petitioner in the year 2008. Considering the nature and ambit of the writ petition, we do not intend expressing any opinion regarding the various allegations against the intervenor. Nor do we intend at this stage of going into the intervener''s competence or his motives. The petitioner is always at liberty to adopt appropriate proceedings against the intervenor if, according to it, the intervenor has acted mala fide or has caused loss to the petitioner. All the rights and contentions between the

petitioner and the intervenor whether relating to this petition or otherwise are kept open.

27. The petitioner would indeed be entitled to raise a serious grievance regarding the intervenor''s allegation that the Appellate Authority heard him in the absence of the petitioner and that it was in view of his submissions that the impugned order was passed by the Appellate Authority. Mr. Kumbhakoni, the learned counsel appearing on behalf of the respondents did not have any instructions in the matter. We are, however, not inclined at this stage to accept the intervenor''s statement which reflects against the Appellate Authority, without giving the Appellate Authority an opportunity of meeting the same. If what the intervenor says is true, it is a matter which requires consideration for the impugned order of far reaching consequences was passed on the basis of the intervenor''s submissions without the petitioner having been afforded an opportunity of meeting the same. The petitioner''s rights in this regard are also kept open. In the circumstances, the impugned orders are set aside. However, the Appellate Authority shall decide the matter afresh. It will be open to the Appellate Authority/Hon''ble Minister to decide the appeal himself or to remand it further to respondent No. 2 for a fresh decision in accordance with law. It will be open to the Appellate Authority or respondent No. 2, as the case may be, to consider whether or not to entertain the intervention application, if any, by the intervenor. It is clarified that this order does not prevent the proposed intervenor from adopting any proceedings in respect of his grievances/allegations. Nor does this order prejudice the suit filed by the intervenor. The petitioner is also at liberty to adopt proceedings against the intervenor. Further, the order does not effect the rights and contentions between the petitioner and the intervenor other than those raised in this petition either.

The writ petition is, accordingly, disposed of. The Chamber Summons is also disposed of. There shall be no order as to costs.

