(2011) 08 AP CK 0053

In the Andhra Pradesh High Court

Case No : WPMP. No. 25173 and 25174 of 2011 In WP. NO. 20720 of 2011

M/s. Indian Immunologicals Limited — APPELLANT

Vs

Union of India and Others — RESPONDENT

Date of Decision : 30-08-2011

Acts Referred:
Drugs and Cosmetics Act, 1940 — Section 18, 21, 22(1), 5, 6
Drugs and Cosmetics Rules, 1945 — Rule 122E, 21, 3, 59, 68

Citation : (2012) 2 ALD 647 : (2012) 3 ALT 85

Hon'ble Judges : Nooty Ramamohana Rao, J

Bench : Single Bench

Advocate : D.V. Sitarama Murthy and Sri Challa Gunaranjan, in Both WPMP Nos. 25173 and 25174 of 2001, for the Appellant; B. Mayur Reddy, in Both W.P. MP Nos. 25173 and 25174 of 2001 for Respondent No. 5 The Additional Advocate General in Both WPMP Nos. 25173 and 25174 of 2001 Counsel for Respondents 2 to 4, for the Respondent

Final Decision : Allowed

Judgement

Sri Justice Nooty Ramamohana Rao

1. This writ petition is instituted by M/s Indian Immunologicals Limited, a subsidiary company of National Dairy Development Board, questioning the legality and validity of the orders passed on 18.07.2011 by the third Respondent-Joint Director & Licensing Authority, Drugs Control Administration, Government of Andhra Pradesh, Hyderabad, canceling the drug manufacturing license of measles vaccine (Abhay-M) in exercise of power available under Rule 85(2) of the Drugs and Cosmetics Rules, 1945.

2. It is stated that the Petitioner was initially established in the year 1983 as a unit of the National Dairy Development Board exclusively for purpose of manufacturing "Foot and Mouth Disease Vaccine". National Dairy Development Board is created in terms of National Dairy Development Board Act, 1987. Subsequently, the Petitioner was incorporated as a company on 08.10.1999

under the provisions of the Companies Act, 1956, and it is a wholly owned subsidiary of National Dairy Development Board. The essential purpose for which the Petitioner company was incorporated was to manufacture and provide various types of vaccines and make them available to the community at an affordable price. The Petitioner company is said to be the second company in the world to develop and launch "Purified Vero Cell Rabies Vaccine". It is asserted that so far no product manufacture by the Petitioner company has come for adverse notice in respect of the standard quality composition thereof. It is stated that the Petitioner company has been granted a license on 16.09.2005 to manufacture various vaccines for utilization of human beings and for their distribution both in domestic market as well as abroad. Initially, the license has been granted for a period of five years valid up to 16.04.2011 and has renewal since been applied for, the Petitioner company is treated to have been granted the necessary renewal.

3. Only two companies in our country are stated to be the manufacturers of measles vaccine, one is the Petitioner and the other, a private company, Serum Institute of India (SII), Pune, Maharashtra State. From the year 2008 onwards, it is stated that the Petitioner company has been supplying the measles vaccine manufactured by it to the Central Government for implementing Universal Immunization Programme undertaken by it. It is stated that upon administering the measles vaccine on 21.08.2010, at Mohanlal Gunj, Lucknow, Uttar Pradesh State, four children died in quick time thereafter. It is stated that the Petitioner company has failed to inform this adverse circumstance to the licensing authority. However, the third Respondent along with several officers of the Drugs Control Administration of the State Government as well as officers of the Central Drugs Standard Control Organisation have conducted inspection of the facilities of the Petitioner company on 17.03.2011 and again from 21.03.2011 to 23.03.2011. This inspection followed another adverse event following immunization of measles vaccine in March 2011 at Gandhidham in Gujarat State. The inspection team appears to have noticed certain discrepancies in the manufacturing facility of the Petitioner company and left certain observations in the inspection notes, for securing corrective measures by the Petitioner company. Apart from sending the vaccine samples collected from the field, samples of vaccines available with the Petitioner have been collected by the inspection team and sent for testing at the Central Drug Testing Laboratory, Kasauli, Himachal Pradesh. In the meantime, pending receipt of the report from the Central Laboratory; the Drugs Inspector of the Drugs Controller Administration of Government of Andhra Pradesh issued orders on 17.03.2011 and 22.03.2011 in terms of Section 22(1)(c) of the Drugs and Cosmetics Act, 1940, directing the Petitioner company not to dispose of the stocks mentioned therein for a period of twenty days and subsequently the said period is extended. It is further averred that the third Respondent-Joint Director along with the officers of the Central Drugs Standard Control Organization along with a vaccine expert from the Central Drugs Laboratory, Kasauli, Himachal Pradesh have once again conducted

inspection of the facilities of the Petitioner on 06.04.2011 and 07.04.2011. It is stated that no critical observations were noticed and no major departure from Good Manufacturing Practices (GMP) were noticed. However, certain observations have been made for making further improvement of the standards of manufacture of vaccines. However, the third Respondent-Joint Director, issued a show cause notice and served it on the. Petitioner on 08.04.2011 calling for the explanation of the Petitioner for various alleged violations mentioned in the said show cause notice. But, without waiting for the reply from the Petitioner, the third Respondent passed orders to stop production of vaccines by the Petitioner company exercising the power available under Rule 85(2) of the Drugs and Cosmetics Rules, 1945. At that stage, stung by the "Stop Production Orders", the Petitioner herein moved W.P. No. 10301 of 2011 and entertaining the said writ petition, this Court passed an order on 15.04.2011 suspending the operation of the "Stop Production Order" subject to the condition that the Petitioner company shall not however supply the vaccines manufactured by it. The Respondents in the said writ petition were directed to finalise the action after receipt of the explanation from the Petitioner company. The writ Petitioner has drawn its explanation on 16.05.2011 and submitted the same. Once again the Respondents 3 and 4 inspected the premises of the Petitioner on 15.06.2011 to 17.06.2011 and 20.06.2011. Thereafter, the impugned order signed'' on 18.07.2011 has been served on the Petitioner on 19.07.2011, canceling the product drug manufacturing license of Measles Vaccine (Abhay-M) granted to the Petitioner earlier under Drug License in Form-28-D. Hence this writ petition has been filed.

4. Heard Sri D.V. Sitarama Murthy, learned senior counsel appearing for Sri Challa Gunaranjan, Learned Counsel for the Petitioner and Sri K.G. Krishna Murthy, the learned Additional Advocate General appearing for Respondents 2, 3 and 4 and Sri B. Mayur Reddy, Learned Counsel who appeared on behalf of the 5th Respondent.

5. It is contended by the learned senior counsel appearing for the Petitioner that, as soon as an adverse event had occasioned, the Government of India in Its Ministry of Health and Family Welfare has ordered for a thorough enquiry and it was found that the measles vaccine manufactured and supplied by the Petitioner company is of standard quality, but, however deaths of children had occasioned due to an erroneous usage of a dilutant , which was unfortunately stored in the same deep freezers where proper diluents are also stored. Therefore, by an accidental mistake instead of using the proper dilutant , an improper one has been used, which lead to the adverse event. In view of the finding that the measles vaccine manufactured by the Petitioner company is of standard quality, no fault would lie with the Petitioner for the deaths of the infants, but all due to an error in programme implementation, such deaths have occurred. Apart from this submission, it is pointed out by the learned senior counsel that the third Respondent has no competence to suspend the license granted to the Petitioner company and such power is vested only with the fifth Respondent. Sri B. Mayur

Reddy, Learned Counsel appearing for the fifth Respondent has taken the same stand that it is the fifth Respondent who has got the power to suspend or cancel the license for manufacture of drugs and pharmaceuticals included in Schedule C and C-1 of the rules and that it has not thought that such an action is warranted.

6. Whereas the learned additional Advocate General would strenuously contend that after introduction of dual licensing system in the Rules, it is the State Drugs Control Administration which is also clothed with the necessary power to grant, to suspend and cancel the manufacturing license granted to the Petitioner.

7. Before analyzing the various rules on which reliance has been placed by both sides, it is only appropriate to set out that the scrutiny of this Court, for the present moment is only confined to the power and competence in the hands of the third Respondent to suspend or cancel the manufacturing license granted to the Petitioner company. After a very detailed consideration was shown to the explanation offered by the Petitioner, (which is a rarity) the impugned order has been passed by the 3rd Respondent, as an obvious result of compelling reaction rooted in larger public interest

8. The Drugs and Cosmetics Act, 1940 (for short henceforth referred to as Drugs Act) is enacted to regulate the import, manufacture, distribution and sale of drugs and cosmetics. Section 3(a)(ii) defined "the board" in relation to drugs other than Ayurvedic, Siddha or Unani drugs as Drugs Technical Advisory Board constituted u/s 5 of the Drugs Act, which is a multi member body. Section 6 of the Drugs Act enjoins the Central Government to establish a Central Drug Laboratory (CDL henceforth), under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by the Drugs Act. Chapter IV of the Drugs Act dealt with various aspects of manufacture, sale and distribution of drugs and cosmetics. Section 16 falling thereunder defines the expression "Standards of Quality" with relation to drug as the one that complies with the standard set out in the Second Schedule to the Act. The Second Schedule appended to the Drugs Act included at serial No. 2 substances commonly known as vaccines, sera, toxins, toxoids etc and the corresponding standard to be complied with by them has been set out as the standards maintained at the International Laboratory for Biological Standards, Stantans Serum Institute, Copenhagen and at the Central Veterinary Laboratory, Weybridge, Surrey, U.K., and such other laboratories recognized by the World Health Organisation from time to time and such further standards of strength, quality and purity, as may be prescribed. Section 18 of the Drugs Act, prohibits manufacture for sale or distribution of any drug which is not of standard quality or is misbranded, adulterated or spurious. Section 17-A defined in clear terms what an adulterated drug is. The manner of appointment of inspectors and their powers have been detailed in Sections 21 and 22 of the Drugs Act. Section 27 provides for penalty for manufacture, for sale or for distribution of any drug deemed to be adulterated, with imprisonment for a term which shall not be les than ten years but, which may extend to imprisonment for life and also shall be

liable to fine which shall not be less than Rs. 10.00 lakhs or three times value of the drugs confiscated, whichever is more. Section 27 thus epitomizes the realization of the statute maker of the potential dangers, the society at large may face all due to manufacturing of adulterated or spurious drugs. Section 33 conferred power on the Central Government to make rules for the purpose of giving effect to the provisions contained in Chapter IV, after consulting the Drugs Technical Advisory Board. In exercise of this power, the Drugs and Cosmetics Rules, 1945, have been framed. It is important to notice the following rules there from.

9. Rules 3(b), 3(f), 59, 68, 68-A, 69, 75, 85 of the Drugs and Cosmetics Rules, 1945, (henceforth referred to as Rules) read as under:

Rule 3(b)

[(b) "drug" includes--

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances (other than food) intended to affect the structure or any function of human body or intended to be used for the destruction of (vermin) or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;]

[(iii) all substances intended for use as components of a drug including empty gelatin capsules; and (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;]

Rule 3(f)

[(f) "manufacture" in relation to any drug 6[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 6[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 retail business; and "to manufacture" shall be construed accordingly;]

Rule 68-A

Grant or Renewal of Licences by the Central Licence

Approving Authority.--

(1) Notwithstanding anything contained in this Part, on and from the commencement of the Drugs and Cosmetics (Ninth Amendment) Rules, 1992, a licence for the manufacture for sale or distribution of drugs as specified from time to time by the Central Government by notification in the Official Gazette, for the purpose of this rule, shall be granted or renewed, as the case maybe, by the Central Licence Approving Authority (appointed by the Central Government.)

Provided that the application for the grant or renewal of such licence shall be made to the licensing Authority.

(2) On receipt of the application for grant or renewal of a licence, the licensing authority shall,-

i. verify the statement made in the application Form;

ii. cause the manufacturing and testing establishment to be inspected in accordance with the provisions of Rule 79; and

iii. in case the application is for the renewal of licence, call for the information(s) of the past performance of the licensee.

(3) If the licensing authority is satisfied that the applicant is in a position to fulfil the requirements laid down in these rules, he shall prepare a report to that effect and forward it along with the application [and the licence (in triplicate) to be granted and renewed, duly completed] to the Central Licence Approving Authority:

Provided that if the licensing authority is of the opinion that the applicant is not in a position to fulfill the requirements laid down in these rules, he may, by order,'' for reasons to be recorded in writing, refuse to- grant or renew the licence as the case may be.

(4) If on receipt of the application and the report of the licensing authority referred to in Sub-rule (3) and after taking such measures including inspection of the premises by the Inspector, appointed by the Central Government u/s 21 of the Act, with or without an expert in the field concerned if deemed necessary, the Central Licence Approving Authority, is satisfied that the applicant is in a position to fulfill the requirements laid down in these rules, he man grant or renew the licence, as the case may be:

Provided that if the Central Licence Approving Authority is of the opinion that the applicant is not in a position to fulfill the requirements laid down in these rules, he may, notwithstanding the report of the licensing authority, by order, for reasons to be recorded in writing, reject the application for grant or renewal of licence,as the case may be.

Rule 69

Application for licence to manufacture drugs other than those specified in Schedules C and C(1) to the Drugs and Cosmetics Rules.

[(1) Application for grant or renewal of licence to manufacture for sale [or for distribution] of drugs, other than those specified in Schedule C and C (1) shall be made to the licensing authority appointed by the State Government for the purpose of this part (hereinafter in this Part referred to as the licensing authority) and shall be made--

(a) in the case of repacking of drugs excluding those specified in Schedule X for sale or distribution in. Form 24-B;

(b) in the case of manufacture of drugs included in Schedule X in Form 24-F;

(c) in any other case, in Form 24.

(2)(a) Every application in Form 24-B shall be made up to ten items for each category of drugs categorized in Schedule M and shall be accompanied by a licence fee of rupees five hundred plus and an inspection fee of rupees two hundred for every inspection or for the purpose of. renewal of the licence.

(b) Every application in Form 24F shall be made up to ten items for each category of drugs categorized in Schedule M and shall be accompanied by a licence fee of rupees six thousand and an inspection fee of rupees one thousand and five hundred for every subsequent inspection or for the purpose of renewal of licence.

(c) Every application in Form 24 shall be made up to ten items for each category of drugs categorised in Schedule M and Schedule M-III and shall be accompanied by a licence fee of rupees six thousand and an inspection fee of rupees one thousand and five hundred for every inspection or for the purpose of renewal of the licence.]

(3) If a person applies for the renewal of a licence after the expiry thereof but within six months of such expiry the fee payable for the renewal of such licence shall be--

i. in the case of Form 24-B a licence fee of rupees five hundred plus an additional fee at the rate of rupees two hundred and fifty per month or part thereof in addition to an. inspection fee of rupees two hundred;

ii. in the case of Form 24-F a licence fee of rupees six thousand plus an additional fee at the rate of rupees one thousand per month or part thereof in addition to an inspection fee of rupees one thousand;

iii. in the case of Form 24 a licence fee of rupees six thousand plus an additional fee at the rate of rupees one thousand per month or part thereof in addition to an inspection fee of rupees one thousand and five hundred;]

(4) A fee of [rupees one thousand shall be paid] for a duplicate copy of the licence issued under Clause (a), Clause (b) or Clause (c) of Sub-rule (1) if the original is defaced, damaged or lost]

(5) Applications for manufacture of more than ten items of each category of

drugs as categorized under Schedule M and M-III or for manufacture of additional items of drugs by licenses in Form 24 or Form 24-F shall be accompanied by an additional fee at the rate of rupees three hundred for each additional item of drug Applications in form 24-B for licence to manufacture for sale and distribution for repacking for more than 10 items of each category or for manufacture of additional items of drugs shall be accompanied by additional fee of rupees one hundred for each additional item of drugs as categorized in Schedule M and M-III.

[(6) Where an application under this rule is for the manufacture of drug formulations falling under the purview of new drug as defined in Rule 122-E, such application shall also be accompanied with approval, in writing, in favour of the applicant, from the licensing authority as defined in Clause (b) of Rule 21.]

Rule 75.

Forms of application for licence to manufacture for sale or distribution of drugs specified in Schedules C and C(1) and X [excluding those specified in Part X-B and Schedule X]___

(1) Applications for the grant or renewal of licence to manufacture for sale or distribution of drugs specified in-Schedules C and C(1) [excluding those specified in Part X-B and Schedule X], shall be made to the Licensing Authority in Form 27 and [shall be made up to ten items for each category of drugs categorised in Schedule M and Schedule M-III and shall be accompanied by a licence fee of rupees six thousand and an inspection of rupees one thousand and five hundred for the purpose of renewal of licences:]

Provided that if the application for the renewal of licence is made after its expiry but within six months of such expiry, the fee payable for renewal of the licence shall be [a licence fee of rupees six thousand plus an additional fee of rupees one thousand per month or apart thereof in addition to an inspection fee of rupees one thousand and five hundred.]

(2) Application for grant or renewal of licence to manufacture for sale or distribution of drugs specified in Schedules C, C(1) and X shall be made to the licensing authority in Form 27-B, and [shall be made up to ten items for. each category of drugs categorized in Schedule M and Schedule M-III and shall be accompanied by a licence fee of rupees six thousand and an inspection fee of rupees one thousand five hundred for every inspection or for the purpose of renewal of licences:]

Provided that the applicant shall possess a licence in Form 28 to manufacture Such drugs:

Provided further that if the application for renewal of a licence is made after its expiry but within six months of such expiry, the fee payable for renewal of the licence shall be [rupees six thousand plus an additional fee of rupees one thousand per month or part thereof in addition to an inspection fee of rupees one

thousand five hundred.]

[(3) The application for grant or renewal of licence to manufacture for sale or for distribution of drugs in [''Large Volume Parenterals'' and Sera and Vaccine and Recombinant DNA (r-DNA) derived drugs] shall be made to the licensing authority appointed under this Part in Form 27-D and [shall be made up to ten items for each category of drugs categorized in Schedule M and shall be accompanied by a licence fee of rupees six thousand and an inspection fee of rupees one thousand five hundred for every inspection or for the purposes of renewal of licenses:]

Provided that if the application for renewal of a licence is made after its expiry but within six months of such expiry, the fee payable for renewal of the licence [shall be rupees six thousand plus an additional fee of rupees one thousand per month or a part thereof in addition to the inspection fee of rupees one thousand and five hundred.]

[(4) A fee of rupees one thousand shall be paid for duplicate copy of the licence issued under Sub-rule (1), Sub-rule (2) or Sub-rule (3), as the case may be, if the original licence is defaced, damaged or lost.

(5) If the licensee applies for manufacture of more than ten items; of each category of drugs, the application shall be accompanied by an additional fee at the rate of rupees three hundred for each additional item of drugs categorized in Schedule M and Schedule M-III.]

[(6) Where an application under this rule is for the manufacture of drug formulations falling under the purview of new drug as defined in Rule 122-E, such application shall also be accompanied with approval, in Writing, in favour of the applicant, from the licensing authority as defined in Clause (b) of Rule 21.]

Rule 85. Cancellation and suspension of licences.__

(1) The Central Licence Approving Authoritu may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part, or suspend it for such period as he thinks fit either wholly or in respect of any of the drugs to which it relates for direct the licensee to stop manufacture. sale or distribution of the Said drugs and [thereupon order the destruction of drugs and] the stock thereof in the presence of an Inspector], if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or rules made thereunder.

(2) The Licensing Authoritu may, for such licences granted or renewed by him, after giving the licensee an opportunity to show cause why such an order should riot be passed, by an order in writing stating the reason therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of any of the drugs to which it relates, [or direct the licensee to stop manufacture, sale or distribution of the said drugs and [thereupon order the

destruction of drugs and] the stocks thereof in the presence of an Inspector] if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or Rules made thereunder.

[(3) A licensee whose licence has been suspended or cancelled by the Central Licence Approving Authority or Licensing Authority under Sub-rule (1) or Sub-rule (2), as the case may be, may within ninety days of the receipt of a copy of the order by him prefer an appeal to the Central Government or the State Government, as the case may be, and the Central Government or the State Government may after giving the licensee an opportunity of being head, confirm, reverse or modify such order.]

(Emphasis is generated by me)

Schedule C listed out various biological products. In the list of such products enumerated thereunder, sera, solution of serum proteins intended for injection, vaccines for parenteral injections, toxins, antigen etc, have been included therein. Schedule C (1) enumerated various other special products. Schedule X contained various other drugs such as Amobarbital, Amphetamine, Barbital, Cyclobarbital, Dexamphetamine, etc. In this context, it will also be appropriate to notice that Schedule M provided for, in great detail, ''good manufacturing practices'' and requirements of premises, plant and equipment for pharmaceutical products.

10. It is not at all in dispute that such of those medicines which are intended either for internal or external use of human beings including those intended for prevention of any disease or disorder answers the description of a "drug". In the instant case, measles vaccine is the product which is licensed to be manufactured by the Petitioner and which license is cancelled by the impugned order. As was noticed supra, entry (1) of Schedule C to the rules included sera, while entry (2) thereof dealt with solution of serum proteins intended for injection and entry (3) in unmistakable terms included vaccines for parenteral injections. As is commonly known, parenteral injections are those meant for human consumption not through the intestines, but through a way which is other than the digestive track. Measles vaccine is hence administered other than by oral consumption. Rule 68-A dealt with the issues relating to grant or renewal of licenses for the manufacture for sale or distribution of drugs specified from time to time by the Central Government by notification in the official gazette for purpose of this rule. It was made clear that, on and from the commencement of the Drugs and Cosmetics (Ninth Amendment) Rules 1992, which were brought into force on 14.12.1992, a license for manufacture for sale or distribution of such drugs shall be granted or renewed by the Central License Approving Authority appointed by the Central Government. Therefore, the power to grant or its renewal, the license for manufacture of drugs for sale or distribution which are notified by the Central Government in the official gazette, is exclusively conferred upon the Central License Approving Authority appointed by the Central Government. The proviso to Sub-rule (1) of Rule 68-A makes it clear that

however the application for grant or renewal of such a license shall be made to the licensing authority. Sub-rule (2) thereof provided for the powers of the licensing authority. Under Sub-rule (3) the licensing authority shall prepare a report recording its satisfaction or its opinion that the applicant shall be granted the license. Thereafter, in terms of Sub-rule (4), the Central License Approving Authority may grant or renew the license or decline to do so. The proviso to Sub-rule (4) makes the position clear by setting out that even though the licensing authority may have recorded his satisfaction on the application, but yet if the Central License Approving Authority is of the opinion that the applicant is not in a position to fulfill the requirements laid down in the rules, for reasons to be recorded in writing, reject the application either for grant or renewal of a license. Thus, when all the four Sub-rules of Rule 68-A are read together, it clearly emerges that the power to grant or renew or to reject a license for manufacture of drugs for sale or distribution is conferred on the Central License Approving Authority and not on the licensing authority. The licensing authority, if he is himself not satisfied that the applicant is in a position to fulfill the requirements, he may for reasons recorded in writing refuse to grant or renew the license. In other words, the proviso to Sub-rule (3) of Rule 68-A confers a power upon the licensing authority to refuse to grant or refuse to renew a license applied for. In case of such satisfaction, it is not needed for the licensing authority to forward his report to the Central License Approving Authority. It stands to reason that such a power to refuse to grant or renew the license is conferred on the licensing authority, in as much as only in the event of his being satisfied that the applicants otherwise fulfills the requirements laid down in the rules, he can draw up a report for consideration of the Central License Approving Authority. In the event the license authority himself is not satisfied, he does not require him to do anything further more. He can straightaway reject the application. Proviso added to Sub-rule (4) clinchingly establishes that the report of satisfaction recorded by the licensing authority does not ipsofacto bring forth the grant or renewal of a license. It is the Central License Approving Authority who has to independently apply his mind and only upon being satisfied that the applicant fulfills all other requirements, he can then grant or renew the license. Thus, when the entire Rule 68-A is read in a proper perspective, it makes the position clear beyond any controversy that the ultimate power either to grant or renew or even refuse to grant is exclusively conferred upon the Central License Approving Authority. Only to the limited extent of refusing to grant or renew a license, power is also conferred upon the licensing authority. Otherwise, the licensing authority has no power either to grant or renew a license for manufacture of drugs for sale or distribution. He can at best make a favourable recommendation for consideration of the Central License Approving Authority. It is appropriate to notice that the power to grant the license partakes with it the power to suspend or cancel the same. Consequently, it is the Central License Approving Authority, which alone can suspend or cancel the license granted for manufacture of drugs for. sale or distribution.

11. Learned Additional Advocate General placed strong reliance upon Rule 69 read with Rule 75 in support of his plea that the Licensing Authority can also exercise the power to cancel a license. Rule 69 dealt with the power to grant or renewal of license to manufacture for sale or distribution of drugs other than those specified in Schedule C and C1 by the licensing authority. It is therefore explicitly clear that power has been conferred upon the licensing authority with regard to grant of license or renewal of license for manufacture of such drugs which are not included in Schedule C and C1. As was noticed already in the instant case, sera and vaccines are included in Schedule C and hence Rule 69 has no applicability with reference to such drugs.

12. Rule 75 no doubt dealt with the forms to be used for applying for a license or a renewal of a license to manufacture for sale or distribution of drugs specified in Schedule C and C1. The said rule makes it abundantly clear that such an application shall be made to the licensing authority in Form 27 or 27-B or 27-D as the case may be. As was already explained supra, the applications are required to be submitted at the first instance to the licensing authority, but however, the same will be considered for grant or renewal or refusal later on by the Central License Approving Authority. Submission of application to the licensing authority is intended to secure the objective of verification / inspection of the facilities available with the manufacturer and the licensing authority can have adequate material before him, upon such verification and inspection, to come to a firm opinion as to whether the applicant fulfilled all the requirements under the rules or not. As was already noticed supra, if the licensing authority himself is not satisfied, he can straightaway record his reasons for such a conclusion and reject the application. Only to this limited extent, the licensing authority has been assigned an independent role. But however, if the license is otherwise deserved to be granted or renewed, such a power is liable to be exercised only by the Central License Approving Authority. In other words, Licensing Authority on his own cannot grant or renew the license applied for by the manufacturer of drugs included in Schedule C and C1. Therefore, submission of applications to the Licensing Authority does not clothe him with any power to suspend or cancel a license.

13. The reliance placed on Rule 85, when examined in the above context makes it clear that it is the Central License Approving Authority who has been conferred the power to cancel or suspend or direct the licensee to stop manufacture, sale or distribution of the drug, for which purposes he was the competent authority to grant or renew the license. In other words, the power to cancel or suspend or issue a direction to a manufacturer to stop production of drugs included in Schedule C and CI is vested only with the Central License Approving Authority. Sub-rule (2) similarly confers the power on the licensing authority, in case he has granted the license or renewed the license as the case may be with reference to drugs other than those mentioned in Schedule C and C1. In the instant case, we are concerned with sera and vaccines which are included in Schedule C of the rules. Hence, I am of the firm opinion that the third Respondent the licensing

authority, lacks clearly the power either to cancel or suspend or order to stop manufacturing drugs for sale or distribution, which are included in Schedule C and C-1.

14. The writ Petitioner has therefore made out a strong case with regard to lack of power of the third and fourth Respondents in this regard. The stand taken by the fifth Respondent in this regard appears to be the correct and tenable one.

15. Further, Sri D.V. Sitarama Murthy, learned senior counsel appearing for the writ Petitioner as well as Sri B. Mayur Reddy, learned additional standing counsel for the Central Government appearing for the fifth Respondent have drawn my attention to the findings of the Central Drug Laboratory, upon analyzing those measles vaccine samples manufactured by the Petitioner company are of standard quality. Therefore, I am satisfied that, though the third Respondent propelled by public interest, has acted in the matter, but however, he lacks the power, competence or jurisdiction to issue the impugned orders.

16. Hence the W.P.MPs are allowed. The writ petition is. admitted. Issue notice returnable in six weeks. Rule Nisi. Call for records.

