(2009) 02 PAT CK 0032

In the Patna High Court

Case No : CWJC No''s. 2425 of 2006

Ranbaxy Laboratories Limited, Plot No. 90, Sector 32, Gurgaon-1222001, Haryana and Another — APPELLANT

Vs

Union of India and Others — RESPONDENT

Date of Decision : 04-02-2009

Acts Referred:
Drugs and Cosmetics Act, 1940 — Section 3, 5, 5(1), 5(2)(i)
Food Corporations Act, 1964 — Section 3(1), 3(2)(a)
Food Safety and Standards Act, 2006 — Section 10, 101, 22, 4, 5

Citation : (2009) 2 PLJR 9

Hon'ble Judges : Navaniti Pd. Singh, J

Bench : Single Bench

Advocate : Rajiv Nayyar, Y.V. Giri, Ajay Singh, Raj Kishore Prasad, Tej Bahadur Roy, K.D. Chatterjee, Amitabh Sohan, Rajeev Ranjan Pd. and Amod Kumar, for the Appellant; S. K. Ghosh, Madhuranand Jha, Nirmal Kumar Sinha and Shail Kumari, for the Respondent

Judgement

Navaniti Pd. Singh, J.—The five writ petitions raise a common question and, as such, have been taken up for final disposal at this stage itself with consent of parties. The question raised is whether the products, as manufactured, stored and marketed by them, are drugs within the meaning of Drugs and Cosmetics Act, 1940, (hereinafter "Drugs Act") thus, requiring statutory compliance of the said Act and the Rules framed thereunder or they are food within the meaning of the Prevention of Food Adulteration Act, 1954 (hereinafter referred to as "Food Act") or they fall under both the Acts. The proceedings emanated from, so far as the first writ application is concerned (Ranbaxy Laboratories Limited), an inspection report dated 30.11.2005 conducted at their godown at Bahadurpur, Kankarbagh Road, Patna wherein the petitioner was directed not to sell some products without licences under the Drugs Act. During pendency of the writ petitions, the Parliament enacted on 23rd August, 2006 the Food Safety and Standards Act, 2006 (Central Act 34 of 2006), thus, the provisions and the applicability of this Act also became a matter to be considered.

2. In various writ applications, different commodities are in question which will be indicated later at an appropriate stage. The Bihar State Drug Controller, in substance, was of the view that notwithstanding these commodities having been accepted as "food" within the meaning of Prevention of Food Adulteration Act., in other States where they were manufactured were "drugs" covered by the Drugs Act and could not be marketed without statutory compliance under the Drugs Act and the Rules framed thereunder. Effectively, the storage for same and marketing of those commodities without drug licence came to be prohibited in this State. When this matter came up before this Court, this Court, on 28.4.2008, inter alia, recorded:-

"The core issues in all these writ applications are whether the articles manufactured and sold by various petitioners, are Drugs covered under the provisions of the Drugs and Cosmetics Act, 1940 or food covered by the Prevention of Food Adulteration Act. The question is of some importance as the authorities in most of the cases outside the State of Bihar have held those articles to be food articles covered by Prevention of Food Adulteration Act whereas the Respondent-Bihar State Drug Controller has held them to be drug as contemplated under the Drugs and Cosmetics Act, 1940.

In my view, the question whether it is a drug as defined by Section 3 of the Drugs and Cosmetics Act or is an item of food or it is covered by both is a matter which should first receive the attention of a technical person who is competent to decide this question at the first instance.

Mr. Rajiv Nayyar learned senior counsel appearing in the case of Ranbaxy Laboratories Pvt. Ltd. submits that the articles sold by his company Ranbaxy Laboratories Pvt. Ltd. are food articles and duly licensed by authority under the PFA Act. The State Drug Controller has erroneously assumed jurisdiction in the matter. Referring to various clarifications and recommendations in their favour and other document that the article is not drug and pointed out that in terms of Section 5 of the Drugs and Cosmetics Act, 1940, a statutory body is there which is chaired by the Director General of Health Services, Government of India, ex-officio. He points out that under the provisions of the PFA Act there is a Central Committee in terms of Section 3 thereof in which again the Director General, Health Services, Government of India is the Chairman ex-officio.

To my mind, this brings about an easy solution wherein the same expert chairs both the committees under both the Acts. Recently there has been a third Act i.e. Food Safety and Standards Act 2006. In the opinion of this Court it is better if first Director General, Health Services, Government of India as noted above who is the exofficio Chairman of both the expert committees should decide whether the articles produced and sold by the petitioner would fall under which of the Acts and what was the obligation of the petitioners because if it is held to be a drug then different standards and considerations are to be applied. Keeping in view public health, if it is a food item then different standards are to be applied if it is covered by the third new Act then again different standards are to be

applied. The public must also know what they are consuming and what the precautions etc. are."

2. In this connection, one may refer to Section 3(1) and Section 3(2)(a) of the Food Act and Section 5(1) and Section 5(2)(i) of the Drugs Act which are quoted hereunder respectively:-

3. The Central Committee for Food Standards.-

(1) The Central Government shall, as soon as may be after the commencement of this Act, constitute a Committee called the Central Committee for Food Standards to advise the Central Government and the State Governments on matters arising out of the administration of this Act and to carry out the other functions assigned to it under this Act.

(2) The Committee shall consist of the following members, namely:-

(a) The Director General, Health Services, ex-officio, who shall be the Chairman; ....

5. The Drugs Technical Advisory Board.-The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.

(2) The Board shall consist of the following members, namely:-

(i) the Director General of Health Services, ex-officio, who shall be the Chairman;....

3. This Court found a common expert under the two subjects whom even the legislature, the Parliament, found competent to be Chairman both under the Food Act and under the Drugs Act and it is because of this expertise legislatively recognized, the Court designated him to take a decision in the matter. Further, the Director General of Health Services, Government of India is the delegate of Central Government who has to ensure implementation of the two Central Acts, the Food Act and the Drugs Act throughout the territory of India, would surely be the right person to decide such a matter which would have an all India repercussions and the Bihar State Drug Controller can only be a subordinate delegate being merely a State functionary within the territorial jurisdiction of a State within the territory of India. The Court must admit that these are highly technical matters having serious repercussions and are better left to experts rather than non-expert Judge. The stand of this Court is inspired by observation of the Apex Court in the case of Tata Cellular vs. Union of India since reported in (1994)6 Supreme Court Cases 651 wherein at page 681 of the reports, the following passage is to be found:-

"It is not the function of a Judge to act as a superboard, or with the zeal of a pedantic school master substituting its judgment for that of the administrator.

The result is a theory of review that limits the extent to which the discretion of the expert may be scrutinized by the non-expert Judge. The alternative is for the court to overrule the agency on technical matters where all the advantages of expertise lie with the agencies. If a court were to review fully the decision of a body such as State board of therapeutics or boggling at the mysteries of the pharmacopoeia''. Such a situation as a State court expressed it many years ago ''is not a case of the blind leading the blind but of one who has always been deaf and blind insisting that he can see and hear better than one who has always had his eye-sight and hearing and has always used them to the utmost advantage in ascertaining the truth in regard to the matter in question."

4. I may also notice here that this order of Court dated 28.4.2008 was passed in presence of all parties including the State of Bihar and the State Drug Controller, as represented by the learned Additional Advocate General Shri S.K. Ghosh, and no party raised any objection nor expressed any reservation in the delegation so made by this Court.

5. It may be put on record that when parties including the Bihar State Drug Controller made their appropriate presentations before the Director General of Health Services, Government of India, he constituted an expert sub-committee, consulted several experts. The expert''s sub-committee met and deliberated which deliberations took time and on request, the court extended the time as earlier fixed by it for a final report to be submitted to the Court by the Director General of Health Services. The respective parties filed their representations before the Director General of Health Services, Government of India, copies of which were made available to the Bihar State Drug Controller. Considering those representations, then the Bihar State Drug Controller filed its detailed comments dated 23.6.2008. Ultimately the report of the Director General of Health Services, inter alia in respect of commodities in dispute, was filed before this Court as additional counter affidavit on behalf of respondents No. 2 and 3 in the 4th case that is CWJC No 5076 of 2006 (Novartis Healthcare Private Limited & Another vs. Union of India & Others). The relevant finding are quoted from the report hereunder:-

"Taking into consideration the observations of the last two meetings the members in the meeting held on 28.7.2008 perused the definition of "drugs" under the Drugs and Cosmetics Act, 1940 and the definition of "food" under PFA Act, 1954 and provisions of the Section 22 of the Food Safety and Standards Act, 2006 (FSSA) which explains the foods for special dietary uses and examined the label/label insert of each of the products under consideration whether they would come under the definition of "drugs" under the Drugs and Cosmetics Act, 1940 or the definition of "food" under PFA Act, 1954 or would be covered under the Food Safety and Standards (FSS) Act, 2006 and observed as under:-

1. M/s Pfizer Limited:

Ferradol- The label was examined and it was observed that there are no

therapeutic claims on the label to suggest that it could treat, prevent, cure or mitigate diseases. Hence it would not come under the definition of drugs.

2. M/s Ranbaxy Laboratories Limited:

Revital- The label/label insert was examined and it was observed that there are no therapeutic claims on the label to suggest that it could treat, prevent, cure or mitigate diseases. Hence it would not come under the definition of drugs.

3. M/s Novartis India Limited:

Resource Renal, Resource Diabetic, Resource Vanilla, Resource High Protein, Resource Junior Vanilla, Resource Dialysis and Santivini Plus- The label/label insert of all the above products were examined and it was observed that there are no therapeutic claims on the labels to suggest that it could treat, prevent, cure or mitigate diseases, hence they would not come under the definition of drugs.

4. M/s Shreya Life Sciences Pvt. Limited:

Beneficial Capsules, CSN Capsules and DSN Capsules-The label of all the above products were examined and it was observed that there are no therapeutic claims on the labels to suggest that it could treat, prevent, cure or mitigate diseases, hence they would not come under the definition of drugs.

5. M/s Alkem Laboratories Ltd.:

A to Z- The label was examined and it was observed that there are no therapeutic claims on the label to suggest that it could treat, prevent, cure or mitigate diseases. Hence it would not come under the definition of drugs.

6. Sushil Kumar Jaiswal:

The representation received from Sh. Sushil Kumar Jaiswal listing the products manufactured by them namely Vimpro Plus, Kidvit-Z, Zencovit Plus, Glucose-C, Samvim Fort, Glucose-D, Kidvit-12, Kidzyme, Samvit-Z, Ferromax, Promac Powder, Proteinmix, Hemplus, Samgoldzym, Samvita, Multidex, Happzyme Fort, Sambidex, Sam Bodygrow, Samdol, Sammalt, Samvitzym, Sambrain Tonic, Sam BPlex, Samenjoy Plus, Samliv, Maccal B-12, Z-Orange and Samcai-12 Vet.

The firm was requested to submit the labels and information with regard to licensing of these products. The firm did not send the requisite labels and information, even the Hon''ble High Court directed the parties to co-operate fully in the matter. The Sub-Committee observed that as the labels have not been received from the firm, same cannot be examined.

7. M/s Cipla Limited did not submit its representation.

Thereafter these products were examined in light of the provisions of the PFA Act, 1954 and it was observed that these products are not conventional food and are not covered under the definition of food prescribed under PFA Act, 1954.

These products however are covered within the provisions of the explanation of Section 212 of the FSS Act, 2006. The regulations to regulate such products have to be made by the Food Safety and Standards Act, 2006 which is under active consideration of establishment. The FSS Act is yet to be enforced/implemented.

After detailed deliberations the subcommittee recommended as follows:-

(i) These products do not come under the purview of definition of drugs under Drugs and Cosmetics Act, 1940.

(ii) These products do not come under the purview of definition of food under PFA Act, 1954.

These products come under the purview of Explanation of Section 22 of the FSS Act, 2006 which has yet to be implemented and regulations to regulate such products have to be formulated by the Food Authority."

6. In view of the findings of the Director General of Health Services, Government of India, the petitioners now have no grievance as, in their view, the matter is settled by the highest authority but the Bihar State Drug Controller sought leave to challenge the same which was found curious by this Court as the Bihar State Drug Controller was a subordinate delegate to the Director General of Health Services. Shri Ghosh, learned AAG-I was, accordingly, heard on this aspect of the matter.

7. Shri Ghosh on behalf of Bihar State Drug Controller submitted (i) that though the matter was entrusted by this Court to the Director General (Health Services), Government of India, he has consulted only authorities under the Food Act but did not consult the authorities under the Drugs Act and, as such, the decision stands vitiated, (ii) once the petitioners had earlier taken out licenses for the products in question as drug, they cannot now be permitted to contend that they are not drug and this contention has not been taken note of which vitiates the decision, (iii) the commodities are drugs and are being sold, labelled as food which has not been properly appreciated by the Director General of Health Services, Government of India and the decision/recommendation is, thus, vitiated, and lastly (iv) that the petitioners, in the guise of food/nutritional supplement under Food Act, are selling the commodities to evade excise duty and provisions of price control by the National Pharmaceutical Pricing Authority which should not be permitted.

8. Now coming to the first submission on behalf of the Bihar State Drug Controller, all that can be said is that this Court found the Director General of Health Services, Government of India to be exofflcio Chairman of both the Expert Committees under the Drugs Act and, as such. a recognized expert authority by the legislature in the matter. This Court, thus, nominated him to resolve the dispute within the two Acts. This Court did not oblige him to consult anybody or any person. This aspect was left to his discretion. Records of different meetings as well as the final report submitted to this Court would show that not only were

authorities under the Food Act consulted but in course of deliberation, there were present Drug Controllers of various States and the Central authority including the Bihar State Drug Controller and at times, different drug licensing authority of Bihar. It is not the case of the Bihar State Drug Controller that their views were not taken or they were excluded from deliberations. Only thing that this Court required was that the petitioners and the State Drug Controller should have their say before the Director General of Health Services, Government of India and it is not in dispute that both had their say. Thus, on these facts, no procedural infirmity can be attributed to the deliberations as held by the Director General of Health Services before coming to a decision in the matter and the objection of the Bihar State Drug Controller cannot be sustained.

9. Now coming to the second contention that once the petitioners had taken out drug licenses for the product, they cannot now be permitted to change their stand, is a contention equally misconceived. There is no estoppel against law. Petitioners may have bona fide acted on a wrong advice and having become wiser, law permitting, changed their stand. The question of estoppel does not arise because it is a question of law and what is the position in law. The expert opinion of the Director General of Health Services vindicates the stand of the petitioners and merely because they had made an erroneous choice earlier would not stop them from correcting their stand. Thus, this aspect is also misconceived.

10. So far as the third contention is concerned, it is based on assumption of the Bihar State Drug Controller that what is being sold is drug in fact even though it is found not to be drug by the Director General of Health Services. After the finding of the Director General of Health Services, Government of India that the commodities are not drugs, it is not open to the Bihar State Drug Controller to contend otherwise and contend that they are in fact drugs being sold labelled as food. This contention is also, thus, misconceived.

11. The last contention is again equally misconceived. Merely because the effect of a commodity being food is that it goes out of price control mechanism or attracts lesser excise duties, is no consideration. In my view, to hold that it would more beneficial to bring it within drugs if it is not otherwise drugs. It is not drug as held by the Director General of Health Services, Government of India, Thus, even this objection of the State is misconceived.

12. The result is that in the scope of judicial review that is available to this Court, the Director General of Health Services, Government of India after considering the various representations and consulting experts having given an opinion, that expert opinion must be respected by this Court. There being no procedural infirmity in coming to the said decision, this Court finds it inappropriate to sit in appeal over the decision for it is well established that in judicial review jurisdiction, Court can look into the decision making process but will not sit in appeal over the decision itself as an appellate authority especially when such technical matters are in issue which are better left to technical experts. The passage from the judgment of the Apex Court, as quoted above from the case of

Tata Cellular (supra), would be relevant here.

13. During pendency of the writ applications, as noted above, the Parliament enacted the Food Safety and Standards Act, 2006. A reference to the said Act and its implications vis-a-vis the products in question has also been subject matter of deliberations by the Director General of Health Services, Government of India. The reason is obvious. Section 97 of the Food Safety and Standards Act, 2006 provides for repeal of enactments as specified in second Schedule to the said Act. In the second Schedule to the Act, the first Act that is to be repelled is the Prevention of Food Adulteration Act, 1954. Thus, it would be seen that the Food Safety and Standards Act, 2006 seeks to repeal and replace the Food Act. But a curious situation as emanated as though the Food Safety and Standards Act, 2006 was enacted by the Parliament on the 23rd of August, 2006, its provisions were not enforced. For the first time, the provisions of Sections 4, 5, 6, 7, 8, 9, 10, 87, 88, 91 and 101 were only enforced with effect from 15.10.2007. The rest of the Act including Section 97 is yet to be enforced. It is pointed out that the matter is before the Apex Court in the shape of Writ Petition (Civil) No. 681 of 2004 (Centre for Public Interest Litigation vs. Union of India & Others) wherein the Central Government has undertaken to enforce parts of the Act at different times and is being monitored by the Apex Court in those proceedings and, therefore, this Court need not labour on that aspect. Suffice to say that the Director General of Health Services has found the products covered by Section 22 of the said new Act and once those provisions are enforced, the obligation of petitioners would squarely fall under that Act but for the interregnum as the petitioners cannot go unregulated in their business of selling commodities of human consumption and they already have licences under the Food Act, those licences wherever obtained, would continue to operate till the time they migrate under the regime of the new Act.

14. In view of the aforesaid, this Court has no option but to accept the report and recommendation of the Director General of Health Services, Government of India and all parties are directed to act in accordance therewith in respect of the products as considered in the report, as reproduced above. The writ petitions are, accordingly, disposed of.

