
(2011) 07 PAT CK 0026

In the Patna High Court

Case No : LPA No"s. 865, 867, 876, 878, 910 of 2009

The State of Bihar

APPELLANT

Vs

Alkem Laboratories Limited

RESPONDENT

Date of Decision : 12-07-2011

Acts Referred:

Citation : (2012) 2 PLJR 80

Hon'ble Judges : T. Meena Kumari, J;Ahsanuddin Amanullah, J

Bench : Division Bench

Advocate : Pushkar Narain Shahi, Ritesh Kumar and Mritunjay Kumar in all cases, for the Appellant; S.A. Narain, Neelma Chatterjee, Namrata Mishra (in 865 and 910); M/s Tej Bahadur Roy, Ajay Singh and Raj Kishore Prasad (in 867 and 876), for the Respondent

Final Decision : Allowed

Judgement

1. Having heard counsel for the parties and considering the averments made in the limitation petition, the delay in filing of these appeals is condoned. Both the counsels have agreed that these matters can be disposed of at the admission stage itself and therefore, these matters are being disposed of accordingly.

2. These appeals have been filed against the common order dated 4.2.2009 passed in C.W.J.C. No. 2425 of 2006, C.W.J.C. No. 6605 of 2006, C.W.J.C. No. 4065 of 2006, C.W.J.C. No. 5076 of 2006 and C.W.J.C. No. 6314 of 2006 passed by learned Single Judge. The writ petitions have been filed by the respondent-laboratories aggrieved by the action of respondent No. 5 in the writ petition with regard to manufacture for sale, storage and distribution of the products by issuing notices as arbitrary and unreasonable.

3. According to the respondent companies, they classified the disputed products which are the subject matter of the notices issued by appellant no.5 (respondent to the writ petition) (The products are large in number hence they have to be called as "Products") long back but there is no direction from any of the

authorities to treat them as "drugs". It is further argued that as they have received the impugned notices, they have to approach this Court for the relief sought for in the writ petition by questioning the issuance of notice also. However, the learned single Judge having observed that this court is not expert body to arrive at such conclusion has chosen to refer the matter to the committee of experts headed by the Director General of Health Services, Govt. of India by calling a report. Accordingly, a report has been submitted to this Court. But, however, the learned single Judge has observed that this Court has no expertise but as the Director General of Health Services, Govt. of India have considered the various representations and after consulting the experts has given an opinion, that expert opinion must be respected by this Court. It has also been observed by the learned Single Judge that there being no procedural infirmity in coming to the said decision, this Court does not find it appropriate to sit as appellate authority over the decision which is well established in judicial review jurisdiction. The Court can only look into the decision making process but will not sit as appellate authority over the decision. When such technical matters are in issue it would be better to refer the matter to the technical experts. Having observed so, the learned Single Judge disposed of the writ petition holding that the respondents companies cannot be unregulated in their business of selling commodities of human consumption for which they have already granted licenses under the Food Control Act. Those licences wherever obtained would continue to operate till the time they migrate under the regime of the new Act. Aggrieved by such observation these appeals have been filed by the State.

4. It has been contended by the learned A.A.G. that this matter has been referred to the Committee of experts headed by the Director General of Health Services, Govt. of India under the Drugs and Cosmetic Act, 1940. The report submitted by the expert would itself indicate that the Committee has come to a conclusion that it is "food" and not "drug" basing on the labels of the products and it was not analyzed in depth with regard to the ingredients of the components on the human body in detail before arriving at a conclusion whether it is "drug" or "food". It is further argued that in absence of such analysis of ingredients by the experts, the report cannot be the basis for coming to the conclusion that the product is "food" not "drug".

5. Per contra it has been argued by Sri S. A. Narain, Sr. counsel for respondent companies that as the report has been submitted by an expert committee headed by Director General of Health Services, Govt. of India as per directions of this Court, this Court cannot sit over on such findings and therefore, needs no interference.

6. Having heard both the parties and on a perusal of the report submitted by Director General of Health Services, Govt. of India, we are of the opinion that in the expert opinion as with regard to labelling of the drugs no material is available before this Court with regard to effect of the composition of such ingredients on the human body, if they are consumed as a "food". Of course, it is the general

parlance that the ingredients generally would be tested on some animals for its ill-effects on the human body before its release in the open market. The perusal of the report indicates the opinion is formed by the experts only in seeing the "labelling" on the products. But there is no indication in the report with regard to the effects, such products would cause on the human body. In the absence of such indication, we are of the opinion that it would-be difficult to arrive at a conclusion whether it can be classified as a "food" or "drug".

7. But, however, in view of the controversy that arose in this case the Director General of Health Services, Govt. of India would take a fresh look into the matter by directing the experts to analyze the ingredients or components of each drug to know the effect of such drugs on the human body. In absence of such analysis, any one cannot come to the conclusion that whether it is a "drug" or a "food".

8. Under the above circumstances, we are of the opinion that the matter can be referred back to the expert committee of the Drug Technical Advisory Board as provided under the Drugs and Cosmetics Act, 1940 and also under the provisions of the Prevention of Food Adulteration Act, 1954 for analyzing the component or ingredients of each products and its effect on the human body if consumed as a food and come to the conclusion whether the products would fall under the classification of the Drugs and Cosmetics Act, 1940 or under the Prevention of Food Adulteration Act as "food".

9. We also make it clear that the Director General of Health Services, Govt. of India should furnish a copy of report to all the parties concerned appearing before this Court and they are entitled to file their objections. We also make it clear that before coming to the conclusion the Director General of Health Services, Govt. of India must consider the objections after affording an opportunity of hearing to them and pass final order with regard to classification, whether products would fall under the definition of "drug" or "food".

10. A contention has been raised by learned A.A.G. with regard to sale price by the companies.

11. We are of the opinion that as the same has not been an issue before the learned Single Judge, the same can not be agitated before us in these L.P.As.

12. We also make it clear that if any of the parties are aggrieved by the order passed by any of the authorities as stated above they can agitate their right before appropriate forum in accordance with law. The entire exercise must be done within a period of six months from the date of receipt of the copy of this order. With the above modification in the order of the learned Single Judge the appeal stands allowed.