PETITIONER:
PRATAP PHARMA (PVT.) LTD. & ANR. ETC. ETC.

Vs.

RESPONDENT:
UNION OF INDIA & ORS.

DATE OF JUDGMENT: 01/04/1997

BENCH:
K. RAMASWAMY, D.P. WADHWA

ACT:

HEADNOTE:

JUDGMENT:

AND

WRIT PETITION (C) Nos.3559 AND 4572/83

O R D E R

These three writ petitions, filed under Article 32 of the constitution of India, raise common question of law, challenging Section 3(h) of the Drugs and cosmetics Act, 1940, as amended by Act 68 of 1982 (for short, the 'Act') with effect from February 1, 1983 as unconstitutional, being arbitrary and violative of Article 14 and 19(1) (9) of the constitution. The grievance of the petitioners is that while the Act amends the definition of "payment and proprietary Medicine" under Section 3(h) of Act, the definition 'drugs' under Section 3(b) read with the definition of "Ayurvedic drug" under section 3(a) has not been changed; as a consequence, there is no prohibition for patenting the Ayurvedic drugs manufactured by the petitioners whereas under the impugned order of the Drug controller dated February 16, 1983 it is so construed and manufacture of those drugs is prohibited. Therefore, the Amendment Act 68 of 1983 and the order passed by the Drug controller, Government of India, are Ultra Vires the legislative power.

Shri M.N. Krishnamani, learned senior counsel and Shri Pankaj Kalra, learned counsel appearing for the petitioners, seeks to support their grievance, but we are unable to agree with the learned counsel. It is seen that patent and proprietary medicine was defined in the pre-Amendment Act under section 3(h) thus:

> "Patent or proprietary Medicine" Means a drug which is a remedy for prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopeia authorised in this behalf by the Central Government after consultation with the Board."

"Drug" had been defined under section 3(b), and continues under the Amendment Act, to read as under:

> "Section 3(b) "drug" includes.

> (i) All medicines for internal or external use of human being or animals and all substances intended to be used for or (in the diagnosis, treatment), mitigation or prevention of disease in human being or animals .....; and
> (ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of (vermin) or insects which cause disease in human being or animals, as may be specified from time to time by the Central Government by notification in the official Gazette."

"Ayurvedic (including Siddha) or Unani Drug" has been defined under section 3(a) of the Act, which reads as under:

> "Ayurvedic (including Siddha) or Unani drug" includes all medicines intended for internal use for or in the diagnoses, treatment, mitigation or prevention of disease in human beings mentioned in, and processed and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic (including Siddha) and Unani (Tibb) systems of medicine, specified in the First Schedule."

Under the Amendment Act 68 of 1983 Section 3(h) has been amended, and reads as under:

> "Patent or proprietary medicine" means-
> (i) in relation to Ayurvedic Siddha or Unani Tibb systems of medicine all formulation containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurvedic, siddha or Unani Tibb systems of medicine, specified in the First schedule but does not include a medicine, which is administered by parental route and also a formulation included in the authoritative books as specified in clause(a);
> (ii) in relation to any other systems of medicine a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian pharmacopoeia authorised in this behalf by the central Government after consultation with the Drugs Technical Advisory Board constituted under section 5."

A reading of these provisions would indicate that prior to the amendment "drug" included all medicines for internal or external use of human beings or animals and all

substances intended to be used for or in diagnoses, treatment, mitigation or preservation of disease in human beings or animals etc. "Ayurvedic Drug" includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings, mentioned in, and processed and manufactures exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic (including Siddha) and Unani (Tibb) system of medicine, specified in the First schedule. While continuing the same system of drugs without any change in the Amendment Act, what has been excluded is the medicine which is administered by parental route; and a formula included in the authoritative books as specified in clause (a) of section 3 is excluded. As a consequence, the necessary result is that any Ayurvedic or Siddha or Unani drug which is administered by parental route and also giving a formula included in the authoritative books specified in the schedule attached thereto stand excluded. Simultaneously, one of the items i.e. 164A relating to Indian medicines is included with which we are not concerned. It is contended that the Ayurvedic, Siddha and Unani systems of medicine are ancient systems and are part of our ancient heritage which provide more lasting and permanent cure to all types of disease or ailments than the transient and instant relief through allopathic medicines. The former are time taking while the latter is instant. However, our systems of medicine must also keep pace with scientific development with modern technology and face cooperative spirit of development. The process and manufacture must go along the developed scientific system. So the drug manufactured by Ayurvedic, Siddha and Unani system of pharmacopoeia for cure of disease must, of necessity, be of standard quality prescribed by the relevant provision of the Act or system of preparation should be certified to be fit for use, sale, storage etc. The administration equally must note that the foreign multi-national pharmaceutical companies are getting our herbal medicine patented and are getting worldwide market which benefit must not be denied to Indians and Indian companies.

The primary question, therefore, is whether such an amendment is ultra vires the provisions of the constitution. Under Entry 19 of list III read with Entry 49 of List I of the seventh schedule, the parliament is competent to enact and to amend the Act. Therefore, the legislative competence is beyond pate of question. The arbitrariness of a legislation violating Article 14 cannot be adjudged to be arbitrary when the Parliament is of the view that it is to ensure safety of the life of human beings or animals. The regulation of manufacture of drug and patenting are necessary and are in public interest as the evil is sought to be remedied by legislative measure. When drugs are administered to human being/animals, they are required to be regulated as adumbrated under the Act. As a consequence, thought by implication the right to practice of medicine or manufacture of the drugs has been guaranteed under Article 19(1) (g) , it is a regulation within the meaning of Article 19(6) of the constitution. As a consequence, it is a reasonable restriction on the right to carry on the trade or business of manufacture of the ayurvedic drugs by the petitioners.

Shri Pankaj Kalra contends that unless there is an express prohibition under the provisions of the Act, the authority cannot infer that there is a prohibition. We are unable to agree with the counsel. If the drug manufactured by the petitioners is found to be in conformity with the

prescribed standard, and is likely to cause injurious to health or to endanger the life of a patient, and therefore, there is no need for an express prohibition under the Act. It is now well settled legal position that regulation includes total prohibition, if it sis found necessary in the public interest. Manufacture of drugs for administration to human beings/animals is regulated by the act and therefore, it attracts Article 19(6). We hold that the Act is intra vires the constitution and does not violate the fundamental rights guaranteed under Articles 14 and 19(1) (g) of the constitution.

The question then arises: whether the drugs manufactured by the petitioners can be prohibited for the purpose of administration to the human beings or animals within the exclusionary clause under section 3(h) of the Act. The question is primarily one of fact, to be decided on the basis of material available. The Drug Controller in the impugned letter has merely opined on the basis of definitions contained, they are prohibitable and therefore, directed that they cannot be manufactured thereafter. There must be evidence on record before the authority to reach a conclusion that the drugs manufactured by the petitioners are prohibitable items under the Act. Unless expert body has gone into and tested these items and decided that the standards adopted by them under the respective pharmacopoeia formula are not consistent with or conformable to the requested established standards and unless it is certified that they are unfit for use of human beings/animals, they are not prohibitable per se. Therefore, the expert body should go into that question and decide which of the items manufactured by the petitioners are conformable to the established standards of pharmacopoeia formula and satisfy the required tests as admissible in that behalf. We are not experts in this field. We cannot hazard to reach a decision on the issue. Though Shri Pankaj Kalra has brought to our notice some of the articles written by persons having knowledge in this branch of science, we do not want to take risk to reach any conclusion on the basis of the above articles. The appropriate course would be that the competent expert body should go into that question and decide the same.

Section 33-C of the Act contemplates constitution of the Expert Body by a committee constituted thereunder by the Government of India. Therefore the Government of India is directed constitute an expert body consisting of experts in the Ayurvedic system of medicine and also some from Allopathy as contemplated under section 33-c. The expert body should go into the question and decide whether the items of drugs manufactured by the petitioners are in conformity with the provisions of the Act and the established formulae in the Ayurvedic Pharmacopoeia. The Government of India or Drug controller, as the case may be, would then take a decision on the basis of its recommendation. In case they find any of these drugs to be injurious to the health of human beings/animals; necessary opportunity would be given to the manufacturers to rectify it; in case they do not rectify the injurious element and the drugs are still found to be so defective as cannot be administered, then necessary orders would be passed prohibition them from manufacturing the same. In the event of such a decision being taken, an opportunity would be given to the persons concerned so that they can also place their material before the committee and thereafter the Drug controller/Board or Government of India, as the case may be, would take a decision on the basis of the expert body's

opinion and the material placed by the petitioners in that behalf.

Since experts in Ayurvedic system of medicine are to be members of the committee to be constituted by the Government of India under section 33-c of the Act, it would be open to the petitioners to suggest to the central Government names of the experts known to them and it is for the central Government to consider whether such person may be drafted as a member of the committee so constituted.

It appears that there is an inter se dispute as to who is entitled to be the proprietor of the petitioner in W.P. No. 4572/83. It appears that the dispute is pending adjudication in the civil court and impleading some of them in this writ petition as representing the petitioner is for the purpose of disposal of the matter pending in this court, It would be subject to the decision by the civil court.

In view of the stay orders granted by this court and as we are remitting the matter to the Government of India, the interim stay would continue till the decision is taken by the Drug controller on the basis of the report submitted by the expert body and the decision to be taken by Government of India/Drug controller. It is needless to mention that since the matters are pending for a long time, the Government of India would constitute the committee as expeditiously as possible and the report may be submitted with in six months from the date of the constitution of the committee.

The writ petitions are disposed of accordingly. No costs.