(1982) 08 DEL CK 0032

In the Delhi High Court

Case No : Civil Writ Appeal No. 1605 of 1981

Hoechst Pharmaceuticals — APPELLANT

Vs

C.V.S. Mani — RESPONDENT

Date of Decision : 13-08-1982

Acts Referred:

Citation : (1983) ILR Delhi 548

Hon'ble Judges : Prakash Narain, C.J;S.S. Chadha, J

Bench : Division Bench

Advocate : A.H. Desai, S.I. Thakori, C.M. Mariar, T.M. Ansari, Rainu Walia, K.M. Iyer, Vijay Rao and K. Prabhakar, for the Appellant;

Judgement

Prakash Narain, C.J.

(1) The import, manufacture, distribution and sale of drugs and cosmetics are, inter alia,regulated by the Drugs and cosmetics Act, 1940, hereinafter referred to as the Act. Sections 6, 12 and 33 of the Act empower the Central Government to frame rules in the manner and to the extent mentioned in the said sections. Such rules have been promulgated and are known as the Drags and Cosmetics Rules, 1945, hereinafter referred to as the Rules.

(2) The Central Government by a notification No. O.S.R.27(E) dated 17/01/1981 made certain amendments to the Rules. The amended rules partly came into force on 1/08/1981 and partly on the date of the publication of the amended rules in the Official Gazette.'' The challenge before us is to these amendments, the contention being that the amendments contained in the notification dated 17/01/1981 are illegal, invalid, ultra virus and unenforceable. The consequent prayer is to quash the said notification and restrain the Central Government and its officers and authorities from taking action in consequence of the amendments postulated by the aforesaid notification amending the Rules.

(3) The four group of petitioners before us in the four petitions are M\\s. Hoechst Pharmaceuticals Ltd. and others(C.W. No. 1605 of 1981), Pfizer Limited (C. W.

No. 1719of 1981), Cyanamid India Limited (C.W. No. 1724 of1981), and Cosme Farma Laboratories (C.W. No. 1951 of1981). The respondents before us are Mr. C. V. S. Mani,Additional Secretary to the Government of India in the Ministry of Health and Family Welfare, New Delhi(under whose signatures the impugned notification has been issued),the Union of India, The Drug Controller, and the Organisation of Pharmaceutical Producers of India. The petitioners are respectively the manufacturers of single ingredient drugs known as "Novalgin" (Hoechst), "Vermex" (Pfizer), "Verban" (Cyanamid) and''''Mejoral" (Cosme Farma). The effect of the amendments in the rules by virtue of the impugned notification is that the petitioners can no longer market their aforesaid drugs under or by giving in any manner upon the labels and containers the trade or brand names under which these drugs have been marketed till the issue of the impugned notification and if the petitioners want to market their said drugs the same can only be marketed if these are Labelle only with their respective proper names, namely, the scientific name by which the respective drug would be known in various pharmacopoea. The impugned amended rules,inter alia, postulate that preparations containing any new drug as the single active ingredient and approved under Rules 30A, 69B or 75B by the licensing authority shall be labelled and marketed under a generic name only. With regard to some other drugs the amended rule provides that the proper name of the drug shall be printed or written in amore conspicuous manner than the trade under the proper which shall be shown immediately after or under the proper name .The dispute really is whether respondents 1, 2 and3, as above-mentioned, can acting within the scope of the power conferred by the Act and the Rules, compel the petitioners or the other manufacturers of drugs to either not use the brand name or trade name at all in marketing the drugs respectively produced by them or can compel manufacturers of drugs to market the drugs by giving proper name or the scientific name more prominently than the brand name or the trade name on the labels or containers. During the course of hearing the second point was not much pressed and the petitioners said that they may even comply with this mandate of the amended rules if otherwise the rules as promulgated are within the power of the rule making authority and the rules were not ultra virus the Act or the Constitution of India. But on the first point, namely complete. prohibition to use the brand name or trade name, the contention is that such prohibition is ultra virus the petitioners'' rights under Articles 13, 14 and 19 of the Constitution. Inasmuch as the arguments in all the four petitions were identical and the facts are not very different for the purposes of enunciating the law, we shall primarily notice the facts in the Hoechst matter ,C.W. No. 1605 of 1981.

(4) The first petitioner is a company registered under the Companies Act, 1956 and is engaged in, inter alia. mamifacture, distribution and marketing of various types of pharmaceuticals .It is also the registered user of various trademarks, including "Novalgin" (bearing registered Trade MarkNos. 148999 and 225514) within the meaning of Section 49 of the Trade Mark and Merchandise Marks Act,

1958, hereinafter referred to as the Trade Marks Act. the second petitioner is the registered proprietor of the trade mark"Novalgin". It is a company registered under the laws of the Federal Republic of Germany. The Second petitioner holds 50 per cent equity of the first petitioner. The third petitioner is a shareholder of the first petitioner and is a citizen of India. The first petitioner under permission of the second petitioner has been using the trade Mark "Novalgin" on its formulations based on the bulk drug "Analgin".The single ingredient drug of "Novalgin" is "Analgin". This bulk drug Analgin is known by the scientific or proper name of Analgin. The bulk drug Analgin also has twn other proper names, viz. "Metamizols" aad "Dipyrone".

(5) The petitioners in the Hoechst matter also claim that they have developed a very effective life saving drug, namely"Betapressin", which is effective in hypertension and cardiac disorders by sophisticated research in development establishments. This drug "Betapressin" has not yet come into the market but apprehending that the impugned notification would apply to the said drug also, the petitioners seek relief in respect of "Betapressin" as well. "Novalgin" i:) already ''in the market for many years.

(6) In our view the petitioners seeking relief in regard to"Betapressin", which they hope to market, is premature and. therefore ,we decline to give any relief with regard to that drug specifically. We will, Therefore, confine our attention to the contentions of the petitioners in relation to their drug known by the brand name or trade name of "Novalgia".

(7) Before we proceed to notice the contentions of the petitioners and the stand of respondents 1, 2 and 3, we may with advantage notice some of the provisions of the Act and the Rules as well as the relevant provisions of the trade and Merchandise Marks Act, 1958, hereinafter referred to as the Trade Marks Act.

(8) Section 1 of the Act is the usual provision giving the name of the Act, the extent of its operation and the date from which it became operative. Section 2 lays down that the provisions of the Act are in addition to and not in derogation of the Dangerous Drugs Act, 1930 (another Act by which manufacture and sale of some drugs are regulated)and any other law for the time being in force(emphasis ours .Section 3 of the Act is the definition section in which many of the words and terms used in the Act have bean Coffined .Section 3(i) defines the word "prescribed" to mean prescribed by the Rules made under the Act. There is noone provision in the Act by which rules can be framed byan authority for the purpose of the entire Act. Rule making power is to be found in and has been made relevant for specific chapters of the Act. Thus, Section 6 of the Act empowers the Central Government to make rules turn provisions in Chapter Ii which would mean for the purposes of effectuating or working out what is contemplated by the provisions contained in Chapter Ii of the. Act. Chapter I Ideals with the Drugs Technical Advisory Board, the Central Drugs Laboratory and the Drugs Consultative Committee contemplated by the provisions contained in Sections 5 to 7A. Chapter Iii deals with import of drugs. Section 8 in this

Chapter defines what is "Standards of quality" for the purposes of the standards of quality contemplated by the various provisions of the Chapter. Section 9 sets out what would be misbranding of drugs for the purpose of Chapter III .Section 9A(e) in terms lays down that it would be misbranding if a drug is not labelled in the prescribed manner. Section 10(b) prohibits import of misbranded drug which in effect means if the drug is branded in any manner other than the prescribed manner. Section 12(1) empowers the Central Government after consultation with the Drugs Technical Advisory Board and after previous publication by notification in the Official Gazette to make rules for the purpose of giving effect to the provisions of Chapter III. There''s a proviso laying down when prior consultation of the Board may be postponed. Section 12(2) apart from the generality of the power given by Section 12(1) specifies the aspects in regard to which rules may specifically be framed. Section 12(2)(l) in terms lays down that rules may be framed to regulate the mode of labelling drugs imported for sale in packages and prescribe the matters which shall or shall not be included in such labels. Section 13 provides that whoever contravenes the provisions of Chapter Iii or of any rule made there under shall, apart from liability under the provisions of Section 11, can also be prosecuted and either imprisoned or fined or both punished by award of imprisonment and fine. Section 14 lays down that where any offence punishable u/s 13 has been committed, the consignment of the drugs in respect of which the offence has been committed shall be liable to confiscation. Chapter Iv deals with manufacture, sale and distribution of drugs in India. Section 16 in this Chapter defines "Standards of quality" to mean in relation to a drug, that the drug complies with the standard set out in the Second Schedule. Section 17 sets out what would be misbranding of drugs covered by Chapter IV. Section 17(e) in terms lays down that if a drug is not labelled in the prescribed manner, i.e. as prescribed by the Rules, it would be a misbranded drug. The concept appears to be the same as in ''Section 9(e) in Chapter III. Section 18 in terms prohibits the manufacturing sale of certain drugs which are not of standard quality or are misbranded or are adulterated etc. Sections 20 to 24 give power to various governmental authorities to analyse and inspect drugs manufactured with the object of distribution or sale. Section 27 in this Chapter makes sale, stocking or exhibiting for sale or distribution of any drug, which is ,inter alia, misbranded or adulterated, punishable with imprisonment and fine. Section 33 in Chapter Iv empowers the Central Government to make rules in the manner and to the extent mentioned therein for the purposes of giving effect to the provisions of Chapter IV. Section 33(2)(i) and(j) read asunder :

"33(2) Without prejudice to the generality of the foregoing power, such rules may (i) prescribe the conditions to be observed in the packing of bottles, packages, and other containers of drugs or cosmetics, and prohibit the sale, stocking or exhibition for sale or distribution of drugs or cosmetics packed in contravention of such conditions ;(j) regulate the mode of labelling packed drugs or cosmetics, and prescribe the matters which shall or shall not be included in such labels "

(9) The only relevant chapter of the Rules which we may notice is Chapter IX.

This Chapter deals with labelling and packing of drugs other than homoeopathic medicines. Rule95 lays down that subject to the other provisions of these Rules ,no person shall sell or distribute any drug(including a patent or proprietary medicine) unless it is labelled in accordance with these Rules. Rule 96, so far as it is relevant. reads as under :

"96. Manner, of Labelling. (1) Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the containers is packed, namely : (i) The name of the drug :For this purpose, the proper name of the drug shall be given in an equally conspicuous manner as the trade name, if any, and shall be (a) for drugs included in Schedule F or ScheduleF(l), the name given therein ;(b) for drugs included in the Indian Pharmacopoeia or the official pharmacopoeias and official compendia of drug standards prescribed in Rule 124, the name or synonym specified in the respective official pharmacopoeias and official compendia of drug standards followed by the letters I.P.'' or, as the case may be, by the recognised abbreviations of the respective official pharmacopoeia and official compendia of drug standards;(c) for drugs included in the National Formulary of India, the name of synonym specified therein followed by the letter ''N.F.I.'' ;(d) for other drugs, the international non-proprietary name, if any, published by the World Health Organisation or where on international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance."

(10) We may now read the relevant portions of the impugned notification. The same read as under : "1. (1) These rules may be called the Drugs and Cosmetics amendment) Rules, 1981.(2) Rule 2(b), rule 2(0), in so far as it relate to the provision of ''preparations containing any drug specified in Schedule W as the single active ingredient'' and rule 3, shall corns into force on the 1st day of August, 1981, and the remaining provisions of these rules shall come into force on the date of their publication in the OfficialGazette.2. In the Drugs and Cosmetics Rules, 1945(hereinafter referred to as the said rules) in rule 96, in sub-rule (1), in clause (i), (a) for the words ''For this purpose,'' the bricketsletters and words ''(A) For this purpose,'' shall be substituted for the words ''the proper name of the drug shall be given in an equally conspicuous manner as the trade name, if any, which shall be'', the words ''the proper name, of the drug shall be printed or written in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name and shall be'' shall be substituted ;(c) after sub-clause (A) as so numbered, the following sub-clause shall be inserted, namely : "(B) The following preparations shall be Labelle only with proper name of the drug and not with any trade name : (i) Preparations containing any new drug as the single active ingredient and approved under rule 30A, 69B or 75B by the licensing authority subject to the condition that such preparations should be marketed under a generic name only.(ii) Preparations containing any drug specified in

Schedule W as the single active ingredient.''3. In the said rules, after Schedule V, the following Schedule dule shall be inserted, namely : Schedule W(See rule 96(l) (i)(B))Name of the drugs which shall be marketed under generic names only: 1. Analgin2. Aspirin and its salts.3. Chlorpromazine and its salts. TD/83-64. Ferrous Sulphate5. Pauperizing and its salts.(No. X-1101317199-D&MS)C. V. S. Mani, Additional Secy."

(11) The only provisions of the Trade Marks Act that we may notice are Section 2(q), Section 25, Section 28 and Section 46. Section 2(q) defines the registered proprietor in relation to a trade mark as the person for the time being entered in the register as proprietor of the trade mark. It Connotes property rights Section 25 lays down that the registration of a trade mark shall be for a period of seven years ,but may be removed from time to time in accordance with the provisions of the said section. Section 28 sets out the rights conferred upon the registered proprietor by virtue of the registration, including the right to exclusively use the registered trade mark. Section 46 provides, inter alia, that if there is discontinuance of the user of a trade mark by the registered proprietor, his name may be removed from the register for non-user bringing the registration of the trademark to an end. This connotes that once the trade mark has been registered, the registered proprietor must use that trade mark on the goods in respect of which the mark is registered and non-user may result in losing the proprietary right or property right contemplated by Section 2(q).These are those which are contemplated or conferred by Sections 25 and 28 of the said Act.

(12) As noticed earlier, the first petitioner manufactures and markets the drug commonly known to the public as Novalgin It is a single ingredient drug in which the bulk drug used is Analgin. According to the petitioner the making and formulation of drugs, even a single ingredient drug ,is a very sophisticated process requiring detailed and precise steps, both in manufacture and quality control, which may vary from manufacturer to manufacturer. It is the petitioners'' case that compliance with official standards alone does not guarantee marketable quality which depends upon the method and control of each manufacture. They contend that for any drug to be effective, inter alia, ''the following conditions need to be fulfilled : (a) the right quality and quantity of dosage ;(b) easy absorption in the system ; and(c) easy excretion without leaving any residues. Thus ,the dosage, the absorption qualities and the excretion aspect are all taken into consideration by each manufacturer to produce the drug it wants to market. It is the petitioners'' case that with the bulk drug Analgin or for that matter Aspirin each manufacturer manufactures the particular formulation of the drug it wants to market and the efficacy of the same, though containing the same bulk drug, may be different in the products of different manufacturers. The finished product containing the same bulk drug will vary in its biopharmaceutical properties depending upon the process ,control, research etc. available with each manufacturer. The assertion is that two products of two manufacturers containing the same ingredient do not necessarily give the two products therapeutic equivalence for a patient. Indeed, the bio-availability, i.e. the therapeutic impact

on a patient of medicines made by different manufacturers may vary in respect of the same patient. This is because of each manufacturer having its own method of preparing and formulating the drug. Thus the quality of the drug is reflected in the brand name which distinguishes each manufacturer''s product from the product of the other. The petitioners have cited authority in respect of this contention and go on to say that a doctor does not prescribe medicine for a disease alone but for a person suffering from the disease. In other words, for the same disease two different patients may be prescribed two different medicines keeping in view the therapeutic impact that a particular medicine may have on a particular patient .It is the petitioners'' case that the drugs made by different manufacturers differ both in their therapeutic equivalence as also in the standards of production and a brand name enables a doctor to make the choice of the precise drug that he wants to prescribe for a patient. Abolition of the brand name, it is contended, would really mean that the choice gets transferred from a professional person with training and knowledge both of the drug and the patient to a nonprofessional trader. It is urged that if drugs are to be sold only by their scientific names or proper names, the trade may even be influenced by the commission or profit margin that each manufacturer may give to the trader. He would not be bothered about the quality of the drug or its therapeutic impact .Indeed, not having seen or known the patient, or having any qualifications to adjudge the patient and the disease with which he is suffering, he would not be in a position to judge the therapeutic impact of the make he dispenses at all. It is further contended by the petitioners that the abolition of brand names by the impugned notification is totally unrelated to the prices of the drug which are under statutory control, by virtue of the drugs (Price Control)Order, 1979.

(13) Novalgin, it is not disputed, is produced both for oral administration and by injection. The petitioners have set out the process at some length but it is not necessary to repeat it here. It is common case that Novalgin has been marketed as such for very many years.

(14) In April, 1975 the Committee on Drugs and Pharmaceutical Industry (commonly known as the Hathi Committee) presented its report to the Parliament. This report,inter alia, dealt with brand names and generic names. The Committee noted the argument about brand names leading to better quality control and suggested that it was necessary that quality control organisations should be tightened up. It, however ,expressed the view that very often drugs which are marketed under brand names are sold at higher prices. The Committee noted that under the earlier Drug Prices(Display and Control) Order, 1966 items with pharmacopoeia names,i.e. generic names, were exempted from price approval. Therefore, the Committee recommended that the formulations based on the drugs for the purpose of generic name used should be free from price regulationand suggested that a beginning should be made with13 drugs changing over to generic names. It noticed that in order to keep the medical profession and particularly the general practitioners well informed about the new drug and

also to popularise the generic names, it was essential to revise the Indian National Formulary and make it up to date and to publish journals on the lines of Prescriber''s Journals published in the United Kingdom and United States of America .The Hathi Committee suggested abolition of brand names in 13 drugs and also recommended that at the same time they should be free from price control. These 13drugs were suggested by way of a beginning in change over from brand names to scientific or proper names or generic names .On 29/03/1978 the Central Government laid on the Table of the Lok Sabha a new Drug Policy. The New Drug Policy while accepting the recommendations of the Hathi Committee, namely that the drug formulations marketed under the brand names should henceforth be marketed under generic names or scientific names, did not accept the recommendation that such drugs should be free from price control. Out of the 13 drugs recommended bythe Hathi Committee with which to start this process, the Drug Policy of 1978 selected five drugs, namely :(i) Analgi''n(ii) Aspirin (Acetyl Salicylic acid)(iii) Chlorpremazine(iv) Ferrous Sulphate and(v) Piperazine and all its salts such as adipate, citrate and '' phosphate. In pursuance of the aforesaid policy the Central Government formulated certain draft rules intending to amend Rule96 of the Rules. These were published in the Gazette of India by two separate notifications dated February 8, 1980and 8/08/1980. Objections and suggestions were invited from all persons likely to be affected by the proposed rules .By the notification dated 8/02/1980 the amendment proposed in Rule 96 was that the proper name of the drug should be printed or written in a more conspicuous manner than the trade name. By the notification dated 8/08/1980 what was proposed was that preparations containing any new drug as a single active ingredient which is approved under certain Rules by the licensing authority should be marketed under the generic name only and should be labelled only with the proper or the generic name of the drug and not with any trade name and also that single ingredient preparations of the aforesaid 5 drugs, namely analgin Aspirin, Chlorpromazine ,Ferrous Sulphate, Piperazine and its salts such as Adipate, Citrate and Phosphate should be marketed under their generic names only. the petitioners claim that by a letter dated May 9, 1980 objections were raised to the proposed amendment to Rule 96.It is further averred that soon thereafter the 4th respondent, the Indian Drug Manufacturers'' Association of India and eminent members of the medical profession made their respective representations to the Central Government. It is alleged that the proposed amendments were opposed as being Contrary to the interest of the public and the pharmaceutical industry. The 4th .respondent is said to have submitted representation in this regard on 19/05/1980, emphasising its earlier representation dated 18/09/1972 and reiterating the stand of the 4th respondent before the Hathi Committee. The petitioner made a further representation dated 21/10/1980 and brought to the notice of the Central Government opinions of prominent authors and experts on the subject. The Central Government, however, in exercise of the powers conferred by Sections 12 and 33 of the Act, by notification dated January 17, 1981, in consultation with the Drugs Advisory

Board, amended Rule96 of the Rules. The effect of the amendment, inter alia,is that drugs specified in the said notification in Schedule''W thereto containing a single active ingredient is required to be labelled only with the proper name of the drug and not with any trade name. The impugned notification further amends the rules to the effect that preparations containing any new drug with a single active ingredient and approved under Rules 30A, 69B and 75B were to be marketed under the generic name only. It is the petitioners'' contention that though representations were made by the petitioners and others, no opportunity of being heard was granted to them by the Central Government. The impugned notification is challenged and in particular amendment to rule 96 is challenged, inter alia, on the following grounds: (1) The amendment is ultra virus the rule making power postulated by Sections 12 and 33 of the Act .Rules can be framed u/s 12 for purposes of Chapter Iii and u/s 33 for the purpose of Chapter Iv only to further the objects of the Act which, according to the petitioners, is to regulate and also prevent, interalia, the manufacture, sale, distribution and storage of drugs in such a manner that spurious or sub-standard drugs are neither manufactured nor marketed and an unwary customer does not fall prey or victim to counterfeit or spuriousdrugs.(2) That though misbranding would include branding in such a manner which is contrary to the rules ,giving of trade name or brand name on the label or packing of a drug cannot fall within the scope of the rule making power. In other words ,by purported exercise of the power conferred by Section 33(1) in framing rules the Central Government cannot impinge upon the law relating to trade mark and prevent the use of trade names or brand names.(3) That prohibition to use trade names or brand names amounts to interference in the proprietary or property rights of the petitioners who a reregistered users or/and proprietors of trademarks. Thus, the impugned amendments amount to infringing property rights of the petitioners.(4) The impugned notification is also vocative of Article 14 of the Constitution inasmuch as there''s no valid classification having a nexus with the objects of the Act in selecting the aforesaid5 drugs in particular and generally in banning use of trade or brand names. The action is per se arbitrary and unreasonable besides being unjust .The notification is liable to be struck down for hostile discrimination both in initially selecting 13 drugs and out of 13 only5 drugs for enforcement of the new policy.(5) The Hathi Committee had made an integrated proposal with regard to abolish of brand names of formulations and making those available at reduced prices. Inasmuch as prices are already under statutory control, even the Committee''s recommendations are not being implemented which amounts to arbitrariness.(6) The impugned notification is also otherwise unreasonable and unjust inasmuch as(a) brand names are absolutely necessary to identify each drug for the consumer;(b) the formulations of the same drug by different manufacturers differ in therapeutic efficacy;(c) at present the choice is with the qualified person like a doctor to choose a specific drug; -(d) the chemist is a trader and would have a profit motive in selecting a drug and will be tempted to push a drug yielding higher margin of profit;(e) the proposal will shift the choice of the drug to a less competent person;(f) the doctor prescribes medicines not

merely for the disease but for a specific person;(g) brand name means that the manufacturer is staking its reputation on the product;(h) abolition of brand name would lead to spurious drugs being brought into the market;(i) Hathi Committee took the view that abolition could be done only when certain conditions were met like after strengthening Drug Control Inspection Organisation and revising theFormulary;(j) the reason of Hathi Committee for abolishing of brand name was that the drugs will become cheaper. This whole basis now disappears by equating such formulation;(k) the experience of other countries like Pakistan shows that abolition of brand names leads to spurious drugs coming into the market;(1) the argument against irrational formulation does not apply to single ingredient drug; and(m) the Drug Organisation is totally inadequate to check sub-standard drugs which will be encouraged .

(15) The rule is opposed by respondents 1,2 and 3. It has been averred that on 8/02/1974 the Ministry of Petroleum & Chemicals constituted a Committee on the Drugs and Pharmaceuticals industry under the Chairmanship ofShri Jaisukhial Hathi to go into various aspects relating to the drugs and pharmaceuticals industry. This Committee submitted its report to the Government in April, 1975.The report contains a large number of recommendations relating to all aspects of the drugs and pharmaceuticals industry. Chapter X of the Hathi Committee report which deals with measures for providing essential drugs and common household remedies to the general public specially in rural areas contains recommendations relating to the substitution of brand names by generic names. The Committee dealt with this subject, though it was not specifically referred to it, asit felt that the question of substitution of brand names of the medicines marketed by the industry by generic names flows clearly from the other terms of reference such as reduction/rationahsation of prices of formulations for the consumers ,making the essential drugs available to the general public, attainment of leadership role by the public sector, promoting the growth of the Indian sector etc. The Committee was also of the view that this question was" directly linked with many important facets of the industry such as drug patents, irrational practice of medicine, excessive use of ingredients in multi-drug formulations, proliferation of such preparations and baneful influence on the medical profession etc. of medicines marketed under brand names." The Hathi Committee having decided to look into this aspect constituted an expert panel of eminent medical specialists. This panel examined the question of substitution of brand names by generic names in all its details and submitted a report to the Committee which in turn examined the matter including facets such as Idealization of brand names, impact of drug prices ,bio-availability, quality of drugs, enforcement of drug control ,multiple ingredient preparations, exports of drugs,labelling difficulties, impact on small scale industry, patent rights ,distribution system, acceptance by the medical profession, role of distributors and pharmacists, effect on the growth of pharmaceutical industry, difficulties and inconvenience in the use of tongue twisting generic names etc.The "Committee also met representatives of the various organisation such as

Indian Medical Association, Organisation of the Pharmaceutical Producers of India, Indian Drugs Manufacturers Association of India, manufacturers'' organisation and members of the Development Council for Drugs and Pharmaceuticals to elicit opinion on these important questions of far reaching significance. Memoranda submitted by State Governments, public sector undertakings as also small-scale sector undertakings and different associations were also considered . After taking into consideration all pros and cons of the problem the Committee came to the conclusion that there was a strong case for substitution of brand names by generic names. The Committee, however, felt that IT would not be advisable to accomplish this change immediately and suggested that brand names should be abolished in a phased manner and a beginning should be made for change over to generic names starting with single ingredient preparations of 13 drugs. The Committee also recommended that the Drugs Controller (India) should, while granting permission ,be requested not to give recognition to brand names of new drugs and the drugs should not be allowed to be marketed under brand names when first introduced in this country. This report was considered by the Central Government in March, 1978 and the report was laid on the Table of the Lok Sabha on 29/03/1978. In pursuance of the decision taken by the Government that brand names should be abolished in a phased manner it was decided that to start with this policy be implemented in respect of five single ingredient drugs and that no new drug should be permitted to be marketed under brand name. Draft amended rules were published on 16/08/1980. The objections and representations received were duly considered and the impugned notification was issued on 17/01/1981.The contentions of the petitioners that the impugned notification impinges upon Articles 14 and 19 of the Constitution and the same is ultra virus the rule making power have not been specifically denied. The impugned notification, however, has been supported by contending that it was within the ambit of the ''rule making power. It is the respondents ''case that justice and fair play requires that the impugned notification should not be struck down as otherwise it would nullify the efforts of the Government of India to encourage the marketing of drugs by their generic names. The counter affidavits sworn by Shri Panchapakesan on behalf of the first three respondents goes on to state, "The multi-national drug cartels of the world are using this country for cashing in on the brand names of their products for the last few decades when the Indian Drug Industry was at its infancy. Now that the Indian drug industry has made phenomenal progress, it is the duty of the Union of India to ensure that the small and medium-scale drug manufacturers in the country should be given equality of opportunity to market the drugs by the generic names and compete with the products of the multi-national companies. So long as these drugs are of pharmacopoeia standards, their therapeutic efficacy can be assured. The claims made by the petitioners that their products are of a much higher standard than the pharmacopoeia standards are of no relevance since it is not proved whether the same are at all necessary for medical use. TheHathi Committee has dealt at length on various steps that the Government of India should take to encourage the Indian small and medium-

scale manufacturers to produce drugs of standard quality. The enforcement of the rule will help in achieving these objectives." At another place in the same affidavit it is said, "The present petition has been filed by the petitioners in order to enable them to continue to dominate the market by virtue of their brand name through sophisticated ,aggressive, high pressure promotional tactics. The drug, namely Novalgin is a prescription drug and the same is available through chemists only on prescription. the petitioner is assuming that the present policy will enable the chemist to push them out of the market. This is, however, not the truth. The medical practitioners are still free to indicate the preference of the manufacturers on their prescription slip (emphasis ours). For example, in the instant case it would read as Analgin-Hoechst". The medical practitioners taught through his medical school period Pharmacology only in generic terms. It is subsequently, during his practice as a medical practitioner, that he is through high pressure salesmanship .It is to curtail this mal-practice that the high-level committee recommended that the brand names be discontinued and drugs be known only in generic terms. For this reason this Hon''ble Court will not exercise its extraordinary power under the Constitution to enable the present petitioners to continue to dominate the market in the drug mentioned hereinabove and for this reason alone the writ petition merits dismissal.

(16) The impugned notification is in pursuance of the decision of the Government of India and will be kept under constant review in the light of actual experience. In the event the respondents find from actual experience that the working of the decision contained in the notification is not satisfactory ,the said notification would be reviewed.

(17) The present restriction sought to be placed by the impugned notification is only on the use of the brand name and not the manufacturing of the drug. The restrictions ought to be placed would also enable other manufacturers of the same drug to have a fair competition with the present petitioners, who are undisputedly the leader of the drug "Novalgin''. The petitioners do not manufacture the basic drug contained in the brand Novalgin. The petitioner buys it mainly from M\\s. Idpl which is the largest drug manufacturer in the whole country. All that the present petitioners do is to market the said drug. The petitioners formulate it into tablet\\injection form and market it under the brand name. From this it would appear that the petitioners are only using their marketing strategy to dominate the market....

(18) Respondent No. 4 in C.W. No. 1605 of 1981 i.e. the Consumer Education and Research Centre, Ahmedabad,which has been allowed to intervene, generally supported the stand of respondents 1, 2 and 3. Its stand is that there is nothing special in the formulations prepared by the petitioner which gets the bulk drug from Indian Drugs and Pharmaceutical Private Ltd. and that the impugned notification would really effectively reduce the price of the drug "Novalgin" which the petitioner produces and markets. It also challenges that the petitioner''s claim about the bio-availability of a drug, particularly like Novalgin, has any

relevance.

(19) Learned counsel for the parties have addressed very illuminating arguments on all the facets of the case. In the view that we are going to take it is neither necessary nor desirable that we comment upon all the aspects on which arguments have been addressed. We would also not like to comment upon whether it is desirable or not desirable to have brand names or trade names. As we have said earlier, we will also not like to express any opinion about "Betapressin" Because it is neither being marketed by the petitioners nor is it one of the five drugs included in the impugned notification. We would like to confine ourselves to examining the scope of the rule making power, whether the impugned notification is ultra virus the Act and the Rules, in the first instance.

(20) The Preamble of the Act, no doubt, says tliat it isan Act to regulate the import, manufacture, distribution andsale of drugs and cosmetics but the real obJect of this Act has been judicially examined on numerous occasions. In Chimanlal Jagjivandas Sheth Vs. State of Maharashtra, , while examining whether substances like absorbent cotton wool, roller bandages and gauze used for or in treatment of diseases fall within the ambit of the Act, it was observed that the Legislature designedly extended the definition of ''drug'' so as to take in substances which are necessary aids for treating surgical or other cases. "The main object of the Act is to prevent sub-standards in drugs, presumably for maintaining high standards of medical treatment. That would certainly be defeated if the necessary concomitants of medical or surgical treatment were allowed to be diluted : the very same evil which the Act intends to eradicate would continue to subsist."

(21) Again, in Indian Chemical and Pharmaceutical Works Vs. State of Andhra Pradesh and Others, , a Constitution Bench of Supreme Court held, "The Drugs Act, 1940, which mainly concerned with standard and quality of drugs manufactured in this country and, Therefore, controls, the manufacture, sale ,and distribution of drugs has nothing to do with duties of excise and with their imposition on narcotics and narcotic drugs."

(22) From the above two observations of Supreme Court it becomes obvious as to what is the real object of the Act and what is the legislative scheme and policy of this enactment .Indeed, the Act. as Section 2 lays down, is in addition to and not in derogation of any other law and the real purpose of the enactment is to ensure quality and standards of drugs manufactured, imported, distributed and sold in the country. If that be correct, as indeed it must beheld to be, we have to read Section 12 and Section 33 giving the rule making power in the above context and of the provisions of Chapter Iii and Chapter Iv of the Act. We have also to see that no rule is made under the Act which is vocative of any other law or impinges upon any other right recognized or conferred by any other law. If a rule impinges upon any other law or any other right, it must be held to be outside the rule making power of the Central Government. Section 2 on the one hand and Sections 12 and 33 of the Act on the other have all to be read together,

being part of the same enactment and part of the same legislative scheme .

(23) As we have noticed earlier. Section 12 confers power on the Central Government, after consultation with the Board and after previous publication by a notification in the Official Gazette, to make rules for the purpose of giving effect to the provisions of Chapter III. Similarly, Section 33 confers a like power to be exercised in the like manner for the purpose of giving effect to the provisions of ChapterIV of the Act. Chapter Iii is concerned with import of foreign drugs while Chapter Iv is concerned with manufacture, sale and distribution of drugs in India. Clause (1)of Section 12 and clause (j) of Section 33 in terms of regulating the mode of labelling packages in which the drugs are offered for sale either after import in one case and after manufacture in the other. The impugned part of Rule 96deals with what is printed or endorsed on such labels Constituting the packages in which the drugs are offered for sale. The question is. Can such restriction be imposed by way of regulating the mode of labelling ?

(24) Farming and promulgation of rules is, as is well-known, subordinate legislation. The grounds on which validity of subordinate legislation can be challenged are by now settled. The challenge may be on the ground that the power to make the law could not have been exercised in the circumstances which were prevailing at the time when the law was made or that the condition precedent to the making of the legislation did not exist or the authority which made the law was not competent to do so or that the law was not made according to the procedure prescribed or that the provisions were outside the scope of the enabling powering the parent statute or were otherwise vocative of its provisions or any other existing statute or a constitutional provision. The impugned portion of Rule 96, it is urged, has-been promulgated outside the scope of the enabling powering Sections 12 and 33 of the Act; it is also vocative of Section 2 of the Act read with the provisory of the TradeMarks Act and is unreasonable restriction as well as having no nexus with the object to be achieved and so impinging the provisions of Article 14 and 19 of the Constitution. It has also been urged that vis-a-vis the petitioners," the impugned rule has also to be struck down on the ground of hostile discrimination. In our opinion, the petitioners contentions on all these counts have great force and the respondents have failed to put forth any cogent argument to refute the claim made.

(25) It is not necessary to dilate on all the points urged before us. Therefore, we shall only touch upon those contentions which, in our opinion, by themselves entitle the petitioners to succeed.

(26) In Chimanlal Jagjivandas Sheth''s case and the Indian Chemical and Pharmaceutical Works, Hyderabad''s case ,noticed by us earlier, the Supreme Court has clearly Stated what is the purpose and scope of the provisions of the Act. Therefore, powers conferred by Section 12 and 33 have to be exercised for effectuating that purpose. For promotion of indigenous drug industry it could be considered a reasonable policy that operations of national companies entering the trade in our country should be prohibited or restricted. This object, however,

is foreign to the scheme and purposes of the Act. If imports are to be banned altogether or are to be made difficult, it would be a negation of the provisions of Chapter III. Indeed, ChapterIII in terms postulates imports. The respondents can make a law or amend any existing law to effectuate the policy which is discerned from the Central Government accepting the report of the Hathi Committee. We are however, unable to appreciate how insisting upon printing or writing of only the generic names could assist in effectuating such policy. The contentions of the respondents in this regard have absolutely no force. No doubt Hoechst, Cyanamid and Pfizer are multi-national companies but they are manufacturing the drugs in question in India. They are not importing the drugs from abroad. The basic drug from which formulations are made is also manufactured in India and obtained by the three companies from the manufacturers in India .How Hathi Committee''s recommendations are relevant in such circumstances is beyond comprehension. The argument completely fails because when we examine the case of one of the five drugs in question, namely, Mejarol.Mejoral, the generic name of which will be Aspirin is manufactured by an Indian Company, namely, Cosme Farme,which has no multi-national links. In this view of the matter ,the impugned amendment has to be held to be arbitrary and irrational and certainly not sub-serving the professed purpose of preventing multi-nationals from dumping their goods in our country. It is then said that the multinational companies by high-powered advertising and marketing techniques are exploiting their trade names. The argument is un-understandable. Mejoral, which is a formulation of aspirin for infants, provides a clear answer to the unacceptability of this stand. The power to regulate labelling cannot be used obliquely to ban imports and that too when it adversely affects drugs which are either not imported or have no connection with trade names used by national companies .Therefore, the exercise of the power must be held to be outside the ambit of the scope of the rules.

(27) The impugned rules must also be held to transgress the scope of the power conferred by relevant clauses of Rules 12 and 33, read with Section 2 of the Act. In terms Section 2 lays down that the provisions of the Act shall bein addition to and not in derogation of the Dangerous Drugs Act and any other law for the time being in force. The Trade Marks Act is a valid law in force. We have earlier noticed the relevant provisions of the Trade Marks Act. Prohibiting the use of trade names under the garb of the power conferred by Section 12 and 33 brings the impugned portion of Rule 96 in conflict with the provisions of the Trade Marks Act. The petitioners, who are proprietors or users of the trade marks, have a right to use their trademarks under the provisions of the Trade Marks Act. Denying them this use not only puts their property rights into jeopardy but is in clear derogation of the rights guaranteed by the provisions of the Trade Marks Act. Therefore, any rule which is framed which would be in "derogation of another valid law cannot be countenanced in view of the provisions of Section 2 of the Act. The rules have to be complementary to the provisions of the Act and the provisions of other valid laws. Rules cannot be in conflict with the provisions

of the Act or the provisions of other valid laws.

(28) The impugned notification must also be held to be one which results in hostel and invidious discrimination. The contentions in this regard are set out in paragraph 19(G), (H), and (1) of the'' petition filed by the Hoechst.Similar contentions have been made in the other petitions also .The Hathi Committee selected 13 drugs set out in Annexure 3 to Chapter X of the Committee Report. These13 drugs were selected by the Hathi Committee for trying out its proposals by way of a beginning and by way of experimentation. This report was accepted by the Central Government. There is no Explanation given in the counter-affidavits filed by way of return as to why the Central Government accepted the report of the Hathi Committee vis-a-vis 13 drugs when there were several other drugs in the same categories which were left out, namely, antibiotics, antipyretics and analgesics .The hostile discrimination is further compounded by the Central Government picking out five drugs to be included in Schedule ''W'' even out of the 13 drugs mentioned by Hathi Committee. On what basis and for what reason these five drugs were picked out by the Central Government is still not explained and the trade, the industry and even we are kept in the dark about it. A reasonable classification is permissible under constitutional provisions. A classification may be reasonable even when a single individual is treated as a class by himself if there are special circumstances or reasons applicable to him alone and not applicable to others, as laid down by the Supreme Court in Ram Krishna Dalmia Vs. Shri Justice S.R. Tendolkar and Others, . No circumstances have been pointed out by the Central Government as to why only five drugs have been included in the Schedule leaving other drugs in the same categories out of it .There is no principle or basis or rational criterion pointed out for doing so. The Hathi Committee had laid considerable stress on placing a control on life saving drugs which according to it should be made available to the consumer at low prices. That appeared to be the basis of there commendations made by the Hathi Committee which byway of example mentioned 13 drugs. The prices are controlled under the Essential Commodities Act by the Drugs(Prices Control) Order. Without amending that order vis-?-vis the five drugs in question the Same have been put in Schedule ''W to implement only a part of the proposal of the Hathi Committee which proposal was an integrated scheme .Why this departure is not known. Why life saving drugs have been left out of Schedule ''W'' is again a mystery. This makes the issue of the notification wholly arbitrary and vocative of Article 14 of the Constitution. The banning of use of the trade name, besides being vocative of the provisions of the Trade Marks Act, as noticed by us earlier, is also vocative of the provisions of Article 19(l)(g) of the Constitution. This provision guarantees to every citizen the right to practice any profession or to carry on any occupation ,trade or business. The factual basis for this contention on behalf of the petitioners is set out in paragraph19, Ground (k) and sub-grounds (i) to (xiv) of the petition filed by Hoechst. Similar submissions have been made in the other petitions also. There is no specific reply to these averments in the counter-affidavit. In our view brand names are absolutely

essential to identify each drug to the consumer .When brand names are used the formulations of different manufacturers are made known to the consumer leaving the choice with the doctor to prescribe a particular drug manufactured by a particular party. It was said on behalf of the respondents that there is no objection to the drug being prescribed by the doctor by its generic name with the manufacturer''s name being indicated. If that be so, it is wholly un-understandable why the brand names cannot be allowed to be used. If brand names aren''t allowed to be used, it interferes with the right to carryon trade or business. The sale of a formulation manufactured by a particular manufacturer would be dependent upon the chemist who for monetary or other reasons may prefer to sell one durg rather than the other. The formulator would be, Therefore, at the mercy of the chemist. The argument about high-powered marketing techniques and advertisement has no relevance in modern India. Surely, itcould not be the respondents'' intention that the Indian formulator with no multi-national connection should continue to market his goods without adopting modern marketing techniques .In any case, the burden was on the respondents to show the reasonableness of the restriction if respondents contend that Article 19 of the Constitution is not violated. They fail to do so.

(29) There is one other aspect on which we would like to comment to show how arbitrary and unreasonable the impugned restriction is. We take the example of Mejoral. This is a formulation of aspirin for infants. It is produced by Cosme Farma. To us it is inconceivable that Mejoralmeant for infants should be sold under the generic name of aspirin alone. A doctor or a parent who wants "BabyAspirin" cannot be left at the mercy of the chemist who may give aspirin meant for adults for consumption by infants .Similarly, we cannot accept the contention that there would be no difference in formulations made by different formulators out of the same bulk drug. High- powered advertisement techniques apart, it is common knowledge and is well supported by medical opinion that two different patients may react differently on taking the same drug. Obviously ,this is because of the difference in what the petitioners call the bio-availability, i.e. therapeutic impact. Respondent No. 4''s contention in support ''of what lias been said by first three respondents that there is no particular difference in therapeutic impact of various formulations manufactured from the same bulk drug cannot be accepted. We are inclined to agree with what the petitioners say because that is not only based on reason but also on experience.

(30) As we have noticed earlier, the petitioners have no objection to giving a generic name along with the tradename and even displaying the generic name more prominently than the trade name. Therefore, holding that the impugned rule is bad in law, we strike down the impugned portion of Rule 96 to the extent that the said five drugs included in Schedule ''W will be marketed only under generic or proper name, Clause (B) of the impugned notification dated 17/01/1981 is held to be illegal and ultra virus of both the Act, other laws and Articles 14 and 19(l)(g) of the Constitution. The impugned amendment in Rule 96 is struck down. The respondents are further directed to amend the said

notification and the maximum restriction that they can put is that the proper name of the drug will be given more prominently than the trade name, as is postulated by clause 2(b) of the impugned notification. No other relief need be granted. The rule is made absolute in the above terms.

(31) The petitioners will be entitled to their costs in each case. Counsel''s fee in each case: Rs. 550.

