

• **IN THE HIGH COURT OF DELHI AT NEW DELHI**

•
Date of Decision: 8th February, 2008

+ **W.P.(C) 5555/1997**

R.S. BHARGAVA PHARMACY Petitioner

versus

UOI Respondent

2. **W.P.(C) 2407/1997**

RALSON REMEDIES PVT. LTD. Petitioner

versus

UOI Respondent

3. **W.P.(C) 3688/1995**

DR. V.K. BHANDARI Petitioner

versus

UOI & ORS. Respondents

4. **W.P.(C) 1791/1998**

HAHNEMANN PHARMACEUTICALS Petitioner

versus

UOI & ORS. Respondents

5. **W.P.(C) 931/2006**

M/S K.R. INDO-GERMAN
HOMEOPATHIC PHARMACEUTICALS Petitioner

versus

UOI & ORS. Respondents

6. **W.P.(C) 19257/2006**

JISHNU PHARMACEUTICALS P. LTD.

..... Petitioner

versus

UOI & ORS.

..... Respondents

Advocates who appeared in the cases :

For Petitioners :

Mr. Ashok Bhasin, Sr. Adv. with Mr. Shantnu Rastogi,
Adv. in WP(C) Nos. 5555/1997, 2407/1997, 1791/1998
Mr. Raman Kapur, Adv. in WP(C) No. 3688/1995
Mr. Kirti K. Mehta, Adv. for Mr. Tarun Dewan, in WP(C)
19257/2006

For Respondents :

Mr. Mukesh Anand, Mr. Shailesh Tiwari, Ms. Zeba
Tarannum Khan, Advs. in WP(C) 19257/2006
Mr. S.K. Dubey, Adv. in WP(C) No. 3688/1995
Mr. Vinod Kumar, Adv. in WP(C) 931/2006
Ms. Monica Garg, Adv. in WP(C) 5555/97, 1791/1998

CORAM:

HON'BLE MR. JUSTICE T.S. THAKUR
HON'BLE MS. JUSTICE VEENA BIRBAL

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| 1. | Whether reporters of local papers may be allowed to see the judgment? | Yes |
| 2. | To be referred to the Reporter or not? | Yes |
| 3. | Whether the judgment should be reported in the Digest? | Yes |

Per Thakur, J

In this batch of writ petitions, the petitioners challenge the constitutional validity of Rule 106B of the Drugs and Cosmetics Rules, 1945 inserted by notification dated 22nd February, 1994. The challenge arises in the following circumstances :-

2. A tragedy resulting in loss of human lives and involving the use of spurious alcohol based medicinal preparations led to the constitution of a one-man Inquiry Committee under the Chairmanship of Justice Jagdish Chandra. Among other recommendations, the Committee suggested that medicinal preparations containing more than 12% alcohol should be packed in smaller packages. These recommendations in turn led to the initiation of a process by which Rule 106B was introduced by way of an amendment to the Drugs and Cosmetics Rules. The Rule so introduced prohibits packing

of homeopathic medicines containing more than 12% Ethyl Alcohol in packings or bottles of more than 30 ml except in cases where the medicine is being sold to hospitals or dispensaries in which case the packings in bottles cannot be of a capacity more than 100 ml. The Rule reads as under:-

106B. Prohibition of quantity and percentage.—No Homeopathic medicine containing more than 12% alcohol v/v (Ethyl Alcohol) shall be packed and sold in packing or bottles of more than 30 millilitres, except that it may be sold to hospitals/dispensaries in packings or bottles of not more than 100 millilitres.”

3. Learned counsel for the petitioners strenuously argued that Rule 106B (supra) is discriminatory inasmuch as it singles out the homeopathic medicines for a hostile treatment. There was, according to the learned counsel, no such provision applicable to allopathic medicines which continue to be packed and sold in bigger containers even when the alcohol content in them may be more than 12%. It was argued that the Rule under challenge placed an unreasonable restriction on the right to free trade and commerce. Besides there was, according to the learned counsel, no justification for the rule making authority to restrict the size of the bottles or the packings nor was there any nexus between the measures enforced by the Government and the mischief sought to be cured by the same. It was also contended that Rule 106B was ultra vires of the provisions of Section 12 of the Drugs and Cosmetics Act, 1940 which did not empower the Government to make a Rule regulating the packaging or the containers to be used for the same. On behalf of the respondents, it was per contra argued that the Rule 106B was intra vires of the Constitution as also the Drugs & Cosmetics Act, 1940. The charge of discrimination was also unfounded according to the learned counsel for the respondent who submitted that the rule was introduced to deal with a mischief which could result in grave danger to human lives if left without remedy or regulation. Three questions, under these circumstances, arise for consideration of this court. These are :

- (i) Is Rule 106B of the Drugs and Cosmetics Rules, 1945 ultra vires of the provisions of the Drugs & Cosmetics Act, 1940?
- (ii) Is Rule 106B discriminatory inasmuch as it regulates containers used only for homeopathic medicines while leaving out preparations under other systems of medicines; and
- (iii) Is the Rule under challenge violative of Article 19(1)(g) of the Constitution of India?

4. We shall deal with the questions ad seriatim :

Re Question No. 1 :

5. Rule 106B of the Drugs & Cosmetics Rules, 1945 introduced by Notification dated 22nd February, 1994 has been framed to regulate the containers in which homeopathic medicines containing more than 12% alcohol is present. The first question that would then arise while examining the validity of the said rule would be whether the rule making authority could exercise the rule making power even in relation to the containers in which the medicine was packed for sale. The answer to that question would primarily depend upon whether the rule under challenge is in any way unrelated or falls outside the objectives which the Act purports to achieve. A reading of the preamble to the Drugs & Cosmetics Act, 1940 would show that the legislation was considered expedient to regulate the import, manufacture, distribution and sale of drugs and cosmetics in India. The term 'manufacture' is defined by Section 3(f) inter alia to mean any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug with a view to its sale or distribution. Section 3(f) may at this stage be extracted:

"3. Definitions

(f) "manufacture" in relation to any drug [or cosmetic] includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug [or cosmetic] with a

view to its [sale or distribution] but does not include the compounding or dispensing [of any drug, or the packing of any drug or cosmetic] in the ordinary course of retail business; and “to manufacture” shall be construed accordingly;]”

6. It is evident from a plain reading of the above that any process or part thereof which deals with packing of drugs or cosmetics is also tantamount to manufacture of drugs and cosmetics. It follows that the Act is intended not only to regulate the import and distribution of sale of drugs but also processes relating to the manufacture which *inter alia* includes packing. In the case of the liquids packing of the medicinal preparations takes place either in glass bottles or other similar containers. Any provision which regulates packing in bottles must necessarily imply regulation of the containers used for such packing. Seen thus, Rule 106B is within the rule making power conferred upon the Central Government under Section 33 of the Act which reserves in favour of the said Government the power to make rules for the purpose of giving effect to the provisions of Chapter IV. If the purpose underlying the Act is also to regulate the packing of the medicinal preparations, any rule which regulates such packing or prescribes the capacity of the bottles/containers in which the same can be packed would clearly be a provision intended to give effect to the provisions of the Act.

7. Even apart from the general power conferred upon the Government in terms of Section 33(1), the provisions of Section 33(2)(i) specifically confer upon the Government the power to regulate packing of the medicinal preparations in bottles, packages and other containers. Section 33(2)(i) of the Drugs and Cosmetics Act, 1940 may, at this stage, be extracted :

“33. Power of Central Government to make rules -

2(i) prescribe the conditions to be observed in the packing in bottles, packages, and other containers of drugs [or cosmetics], [including the use of packing material which comes into direct contact with the drugs] and prohibit the sale, stocking or exhibition for sale, or distribution of drugs [or cosmetics] packed in contravention of such conditions;”

8. There is in the light of the above, no room for holding that Rule 106B which regulates the packing of homeopathic medicines in bottles is outside

the rule making authority vested in the Government under Section 33 of the Drugs & Cosmetics Act, 1940 and hence ultra vires of the said Act. Not only from the stand point of the Rule in question giving effect to the provisions of the Act but also from the stand point of the specific power vested in the rule making authority under Section 33(2)(i), Rule 106B is intra vires of the Act.

9. Although the scheme of the Act and a plain reading of the provisions contained in the same leave no manner of doubt that Rule 106B is within the rule making authority of the Government, we may briefly refer to a few decisions of the Supreme Court in which the Court has stated the principles to be applied while dealing with a challenge to a piece of delegated legislation on the ground that the same falls beyond the authority conferred upon the delegate.

10. In ***Maharashtra State Board of Secondary and Higher Secondary Education and Anr. V. Paritosh Bhupeshkumar Sheth and Ors.*** AIR 1984 SC 1543, the court declared that while examining whether a particular piece of delegated legislation, whether in the form of a rule or regulation or any other type of statutory instrument, was in excess of the power of subordinate legislation conferred on the delegate, has to be determined with reference only to the specific provisions contained in the relevant statute conferring the power to make the rule, regulation etc. and the object and purpose of the Act as can be gathered from the various provisions of the enactment. It was wrong, the Court observed, for their Lordships to substitute its own opinion for that of the legislature or its delegate as to what principle or policy would best serve the objects and purposes of the Act and to sit in judgment over the wisdom and effectiveness or otherwise of the policy laid down by the regulation making body and declare a regulation to be ultra vires merely on the ground that, in the opinion of the Court, the impugned provisions will not help to serve the

object and purposes of the Act. The following passage from the said decision sums up the legal position succinctly :

“So long as the body entrusted with the task of framing the rules or regulations acts within the scope of the authority conferred on it, in the sense that the rules or regulations made by it have a rational nexus with the object and purpose of the Statute, the court should not concern itself with the wisdom or efficaciousness of such rules or regulations. It is exclusively within the province of the legislature and its delegate to determine, as a matter of policy, how the provisions of the Statute can best be implemented and what measures, substantive as well as procedural would have to be incorporated in the rules or regulations for the efficacious achievement of the objects and purposes of the Act. It is not for the Court to examine the merits or demerits of such a policy because its scrutiny has to be limited to the question as to whether the impugned regulations fall within the scope of the regulation-making power conferred on the delegate by the Statute. Though this legal position is well established by a long series of decisions of this Court, we have considered it necessary to reiterate it in view of the manifestly erroneous approach made by the High Court to the consideration of the question as to whether the impugned Clause (3) of Regulation 104 is ultra vires.”

11. Reference may also be made to the decision of the Supreme Court in ***V.T. Khanzode and Ors. v. Reserve Bank of India and Anr.*** AIR 1982 SC 917, where the court observed thus :

“It is well-settled that where a specific power is conferred without prejudice to the generality of a power already conferred; the specific power is only illustrative and cannot restrict the width of the general power.”

12. It is, in the light of the above settled legal position futile for the petitioners to argue that Rule 106B was beyond the rule making power delegated to the Government under Section 33 of the Act. It is noteworthy that the petitioners did not challenge the validity of the rule on the ground of violation of the procedural formalities required to be followed by the delegate in making the rule. The record, however, bears sufficient evidence of the fact that the Government had while introducing Rule 106B, consulted the Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940. It is also evident from the record that before promulgating the rules, the rule making authority had invited objections from the affected parties and the same were considered at the

appropriate level. There was therefore no legal infirmity in the framing of the rules, to call for any interference from this Court. Our answer to question No.1 is therefore in the negative.

Re Question No. 2 :

13. The challenge to the rule on the touchstone of the equality clause contained under Article 14 of the Constitution is also in our view wholly untenable. We say so because the legal position in regard to the permissible classification is fairly well settled by a long line of decisions rendered by the Supreme Court. In ***Budhan Choudhry and Ors. Vs. The State of Bihar*** AIR 1955 SC 191, the Supreme Court authoritatively held that Article 14 does forbid class legislation but does not forbid reasonable classification for purposes of legislation. The Court in that case evolved the dual test of the classification being founded on an intelligible differentia which distinguishes persons or things that are left out of the group and the differentia having a rational nexus to the object sought to be achieved by the statute in question. The Court declared that classification can be founded on different basis, viz; geographical according to the objects or occupations or the like. What was necessary, observed their Lordships, was that there must be a nexus between the basis of classification and the object of the Act under consideration. The law was summed-up by the Court in ***Ram Krishna Dalmia v. Shri Justice S.R. Tendolkar and Ors.*** AIR 1958 SC 538 in the following paragraph which we may gainfully extract :

- “(a) that a law may be constitutional even though it relates to a single individual if, on account of some special circumstances or reasons applicable to him and not applicable to others, that single individual may be treated as a class by himself;
- (b) that there is always a presumption in favour of the constitutionality of an enactment and the burden is upon him who attacks it to show that there has been a clear transgression of the constitutional principles;
- (c) that it must be presumed that the legislature understands and correctly appreciates the need of its own people, that its laws are directed to problems made manifest by experience and that its discriminations are based on adequate grounds;
- (d) that the legislature is free to recognise degrees of harm and may confine its restrictions to those cases where the need is

deemed to be the clearest;

(e) that in order to sustain the presumption of constitutionality the court may take into consideration matters of common knowledge, matters of common report, the history of the times and may assume every state of facts which can be conceived existing at the time of legislation; and

(f) that while good faith and knowledge of the existing conditions on the part of a legislature are to be presumed, if there is nothing on the face of the law or the surrounding circumstances brought to the notice of the court on which the classification may reasonably be regarded as based, the presumption of constitutionality cannot be carried to the extent of always holding that there must be some undisclosed and unknown reasons for subjecting certain individuals or corporations to hostile or discriminating legislation." (emphasis supplied)

14. We may also refer to the decision of the Supreme Court in ***Sakhawat Ali v. State of Orissa*** AIR 1955 SC 166, where their lordships observed that it was for the legislature to determine what categories it would embrace within the scope of legislation and merely because certain categories standing on the same footing as those which are covered by the legislation are left out would not render the legislation discriminatory or violative of the fundamental rights guaranteed under Article 14. The court observed :

"The simple answer to this contention is that the legislation enacted for a particular object or purpose need not be all embracing. It is for the legislature to determine what categories it would embrace within the scope of legislation and merely because certain categories which would stand on the same footing as those which are covered by the legislation are left out would not render legislation which has been enacted in any manner discriminatory and violative of the fundamental right guaranteed by Article 14 of the Constitution."

15. In ***V.K. Sood v. Secretary, Civil Aviation and others*** AIR 1993 SC 2285, the Supreme Court declared that no motives could be imputed to the legislature and that a rule could not be struck down as invalid on the ground of mala fides. The Court observed :

"The rules thus having been made in exercise of the power under proviso to Article [309](#) of the Constitution, being statutory, cannot be impeached on the ground that the authorities have prescribed tailor-made qualifications to suit the stated individuals whose names have been mentioned in the appeal. Suffice to state that it is settled law that no motives can be attributed to the Legislature in making the law."

16. It is not, in the light of the above legal position, open to the petitioners to contend that Rule 106B was discriminatory in nature simply because the rule making authority had left out preparations in other systems of medicines from a similar restriction as to the capacity of the container in which the same could be sold. There is no gainsaying that Homeopathic, Ayurvedic, Allopathic, Unani and other systems of preparations are totally different in their content and approach. Just because another system of medicine also makes use of alcohol for its medicinal preparations but has been left out of the regulatory control introduced by Rule 106B would not render the said rule discriminatory qua Homeopathic medicines with more than 12% alcohol content. The very fact that the systems of medicines are different would in our opinion justify a different approach to each one of them. Inasmuch as the rule making authority chose to regulate containers used for marketing homeopathic drugs only, leaving out drugs manufactured in other systems of medicines making use of alcohol, would not render the rule constitutionally invalid on the ground of discrimination, being contrary to Article 14. Our answer to question number 2 also, thus, is in the negative.

Re Question No.3 :-

17. The right to carry on any trade, occupation or profession guaranteed under Article 19(1)(g) of the Constitution is not absolute in terms. Reasonable restrictions can be placed upon the said right in the interest of general public. The legal position in this regard is fairly well settled by a constitution bench decision of the Supreme Court in ***Khoday Distilleries Ltd. and Ors. v. State of Karnataka and Ors.*** (1995) 1 SCC 574, where the court observed :

“The rights protected by Article 19[1] are not absolute but qualified. The qualifications are stated in Clauses [2] to [6] of Article 19. The fundamental rights guaranteed in Article 19[1](a) to (g) are, therefore, to be read along with the said qualifications. Even the rights guaranteed

under the Constitutions of the other civilized countries are not absolute but are read subject to the implied limitations on them. Those implied limitations are made explicit by Clauses [2] to [6] of Article 19 of our Constitution.”

18. Their lordships were in that case dealing with restrictions placed on the trade and business in industrial alcohol and in medicinal and toilet preparations containing liquor and alcohol. The Court held that restrictions placed on the use of alcohol in medicinal and toilet preparations could be regulated and that restrictions placed on the use of alcohol intended to prevent the abuse or diversion thereof were reasonable in nature.

19. In ***Municipal Corporation v. Jan Mohd. Usmanbhai*** (1986) 3 SCC 20, the court interpreted the expression “in the interest of general public” and held that the same were of wide import comprehending public order, public health, public security, morals, economic welfare of the community and the objects mentioned in part IV of the Constitution.

20. In ***Cooverji B. Bharuch v. Excise Commissioner***, AIR 1954 SC 220, the court was examining the test applicable for determining the reasonableness of the restriction and observed that reasonableness of the restriction has to be determined by reference to the nature of the business and the conditions prevailing in the trade. Some occupations by the noise made in their pursuit, some by the odours they engender, and some by the dangers accompanying them, require regulations as to the locality in which they may be conducted.

21. In ***Mohd. Hanif Quareshi and Ors. v. The State of Bihar*** AIR 1958 SC 731, the court was examining the test to be applied for determining the reasonableness of the restriction and observed :

“Clause (6) of Art. 19 protects a law which imposes in the interest of the general public reasonable restrictions on the exercise of the right conferred by sub-clause (g) of clause (1) of Art. 19. Quite obviously it is left to the court, in case of dispute, to determine the reasonableness of the restrictions imposed by the law. In determining that question the court, we conceive, cannot proceed on a general notion of what is reasonable in the abstract or

even on a consideration of what is reasonable from the point of view of the person or persons on whom the restrictions are imposed. The right conferred by sub-clause (g) is expressed in general language and if there had been no qualifying provision like clause (6), the right so conferred would have been an absolute one. To the person who has this right any restriction will be irksome and may well be regarded by him as unreasonable. But the question cannot be decided on that basis. What the court has to do is to consider whether the restrictions imposed are reasonable in the interests of the general public. (emphasis supplied)

22. Similarly in ***Bishambhar Dayal Chandar Mohan and Ors. v. State of Uttar Pradesh and Ors.*** AIR 1982 SC 33, the court reiterated the principle underlying clauses 5 and 6 of Article 19 and observed that reasonable restriction signifies that the limitation imposed on a person in enjoyment of the right should not be arbitrary or of an excessive nature, beyond what is required in the interests of the public. The court also held that the test of reasonableness, wherever prescribed, should be applied to each individual statute impugned, and no abstract standard, or general pattern of reasonableness can be laid down as applicable in all cases. The following passage from the decision is in this regard apposite :

“The expression 'reasonable restriction' signifies that the limitation imposed on a person in enjoyment of the right should not be arbitrary or of an excessive nature, beyond what is required in the interests of the public. The test of reasonableness, wherever prescribed, should be applied to each individual statute impugned, and no abstract standard, or general pattern of reasonableness can be laid down as applicable in all cases. The restriction which arbitrarily or excessively invades the right cannot be said to contain the quality of reasonableness and unless it strikes a proper balance between the freedom guaranteed in Article 19(1)(g) and the social control permitted by Clause (6) of Article 19, it must be held to be wanting in that quality.

In judging the validity of these restrictions, the Court has to strike a proper balance between the freedom guaranteed under Article 19(1)(g) and the social control permitted by Article 19(6).”

23. Reference may also be made to the decision of the Supreme Court in ***Southern Pharmaceuticals and Chemicals, Trichur and Ors. v. State of Kerala and Ors.*** AIR 1981 SC 1863 where the court reiterated the settled legal position that no fundamental right was available to a citizen under Article 19(1)(g) of the Constitution to carry on trade in any noxious

and dangerous goods like intoxicating drugs or intoxicating liquors. The Court observed :

“The power to legislate with regard to intoxicating liquor carries with it the power to regulate the manufacture, sale and possession of medicinal and toilet preparations containing alcohol, not for the purpose of interfering with the right of citizens in the matter of consumption or use for bona fide medicinal and toilet preparations, but for preventing intoxicating liquors from being passed on under the guise of medicinal and toilet preparations. It was within the competence of the State Legislature to prevent the noxious use of such preparations, i.e. their use as a substitute for alcoholic beverages.”

24. The court further held that it was a matter of common knowledge that Ayurvedic preparations like asavas and arishtas containing liquor are always likely to be misused as a substitute for alcohol beverages and therefore the restriction imposed by Section 12A of the Abkari Act, 1977 was a reasonable restriction within the meaning of Section 19(6) of the Constitution. The following passage is in this regard instructive :

“The contention that Note to Rule 3(1) is an unreasonable restriction on the freedom of trade guaranteed under Article [19\(1\)\(g\)](#) of the Constitution has no substance. It provides that unless otherwise declared by the Expert Committee, asavas and aristas and other preparations containing alcohol are deemed to be spurious if their self-generated alcoholic content exceeds 12% by volume. It is a matter of common knowledge that such preparations are always likely to be misused as a substitute for alcoholic beverages and, therefore, the restriction imposed by Section 12A is a reasonable restriction within the meaning of Section 19(6) of the Constitution.”

25. In the light of the above pronouncements of the Supreme Court, we have no hesitation in holding that the restriction placed upon the use of containers for sale of homeopathic medicines with more than 12% alcohol content in the same is a reasonable restriction and is intended to prevent misuse of such preparations by those who purchase the same across the counters. The experience of such preparations having been misused in the past leading to loss of valuable human lives was, in our view, sufficient for the rule making authority to act in public interest and regulate the sale of such medicines by stipulating that they would not be sold in containers more than 30 ml capacity. The rule, it is noteworthy, does not require such small containers to be used in case the supply is meant for hospitals and

dispensaries in which event the packing of bottles could be of 100 ml also. Having regard to the purpose sought to be achieved by the Act and the Rules framed thereunder, the restriction contained in Rule 106B qua homeopathic medicine with more than 12% alcohol content cannot be said to be either unreasonable or otherwise violative of the right guaranteed to the petitioners under Article 19(1)(g) of the Constitution. Our answer to question No. 3 is in the negative.

26. In the result, these petitions fail and are hereby dismissed but in the circumstances without any order as to costs.

T.S. THAKUR, J.

VEENA BIRBAL, J.

FEBRUARY 08, 2007
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