(1996) 04 DEL CK 0040

In the Delhi High Court

Case No : Civil Writ Petition No. 2108 of 1995

Corporate Channels India (P) Ltd. APPELLANT

Vs

Union of India RESPONDENT

Date of Decision : 17-04-1996

Acts Referred:
Constitution of India, 1950 — Article 14, 19, 21, 226
Drugs and Cosmetics Act, 1940 — Section 25(4), 3, 6
Drugs and Cosmetics Rules, 1945 — Rule 3, 3

Citation : (1996) 3 AD 500 : AIR 1996 Delhi 375 : (1996) 37 DRJ 261

Hon'ble Judges : Y.K. Sabharwal, J;D.K. Jain, J

Bench : Division Bench

Advocate : S.K. Kaul, N.K. Kaul, Rakesh Tikku, Mukul Rohatagi, Rajiv Nayar and F. Malik, for the Appellant;

Judgement

D.K. Jain, J.

(1) Keeping in view the urgency of the matter, with the consent of counsel for the parties, we proceed to dispose of the writ petition at this stage itself.

(2) The petitioners, manufacturers of tube rings, (one of the contra ceptive devices used in female sterilisation), under the brand name "EVE''S", have filed this writ petition under Article 226 of the Constitution seeking a writ in the nature of mandamus directing respondent No.1 to consider their product for purchase and distribution to the public along with the product of other suppliers. They also seek a writ of prohibition restraining the said respondent from placing order for purchase of tube rings which do not conform to standards specified by Bureau of Indian Standards (for short the BIS) and in particular restraining them from accepting against payment any supplies of Kli brand tube rings from respondent No.2 under the second purchase order placed in October 1994, until the pre-procurement sampling and testing of-their product is done by the Central Drug Laboratory (for short the CDL).

(3) The first petitioner is a Private Limited (company and the second petitioner is

one of its shareholders. There arc two respondents - Union of India through Department of Family Welfare, Ministry of Health and Family Welfare, New Delhi is the first respondent and one M/s Cabot Medical Corporation, Usa through its local agents M/s Aravali International Pvt. Ltd., New Delhi is the second respondent.

(4) The grievance of the petitioners is that acting on the specific representations held out by respondent No.1 in February/March 1992, to the effect that it will purchase only those tube rings which meet the standards laid by the his and preference would be given to indigenous products, they established an industrial unit, by investing large sum of money, for the purpose of manufacturing tube rings for National Family Welfare Programme; went into production; their product was evaluated by the Iit, the notified Cdl, and approved on 3 March 1994 as conforming to his Standard IS: 13009:1990, but respondent No.1 has now declined to consider their product for purchase and distribution and instead had been and are still insisting on purchasing Kli brand tube rings from respondent No.2 in spite of the fact that as per the report of the Cdl their product does not meet the his standards. It is averred that: respondent No.1 placed with respondent No.2, two orders for purchase of ten lakh pairs each of their Kli brand tube rings for a total value of approximately Rs.5.8 crores in August - October, 1994; the first supply valued at approximately Rs-1.2 crores, received in October 1994, was tested at the Cdl but failed the test; similarly the second supply, received in November 1994, also failed evaluation test conducted by the CDL; thereafter, the Drug Controller of India and some other officials visited USA; approved another laboratory there; got respondent No.2''s product tested in that laboratory and gave clearance for acceptance of the tube rings supplied by respondent No.2, notwithstanding the adverse report of CDL. It is alleged that the normal procedure prescribed for purchase of tube rings was and is being flouted by respondent No.1 with a view to illegally benefit respondent No.2.

(5) The petitioners also claim that on the strength of the certificate issued by Cdl and the inspection carried out on 14 February 1994 of their factory by a team constituted by the Drug Controller, they have made supplies of tube rings to various State Governments but so far no complaint has been received.

(6) Thus, according to the petitioners the conduct of respondent No.1 in not considering the petitioners'' product for purchase and giving preference to the product of respondent No.2: (i) is arbitrary, illegal and in violation of Articles 14, 19(l)(g) and 21 of the Constitution; (ii) the petitioners having altered their position relying on the representation that only those tube rings would be purchased which meet the Indian standards IS: 13009:1990 and preference would be given to the indigenous products, put heavy investment and effort to si:t up their unit, on the principle of promissory estoppel, it is not open to respondent No.1 to reside from that position and they are now estopped from making purchases in contravention of the specific assurances; and (iii) if respondent No.1 is permitted to continue making purchases from respondent

No.2, it would not only be in violation of the provisions of the Act, but will also ruin the local industry besides loss of precious foreign exchange to the Government.

(7) While issuing notice to show cause as to why rule nisi be not issued, as an interim measure, it was directed that for future orders, the product of the petitioner should also be considered. Thereafter it was also directed that if the goods supplied by respondent No.2 did not conform to IS: 13009: 1990 standard, the same shall not be distributed. The interim orders still continue.

(8) The petition is resisted by the respondents by filing affidavits in reply. In the counter filed on behalf of respondent No.l, while admitting that the his specifications under the provisions of the Act and the Rules made thereunder, have been adopted for quality assurance, it is, inter alia, contended that: (i) any change or modification in the his specifications is enforceable only if followed by a gazette notification; (ii) petitioners'' product being a new drug, has not been subjected to clinical trials in accordance with the specifications prescribed under the Act and Rules made there under and, Therefore, it is not possible to purchase their product; (iii) in the absence of clinical trials, the Cdl, that is, the I I T did not follow the full procedure while certifying that petitioners product conforms to IS: 13009 and (iv) since the petitioners were not represented in the meetings held in February/March, 1992 and then in November 1992, there was no question of holding out assurance of any kind to them and in any case their internal discussions do not tantamount to assurance to the petitioner or any other person in this trade.

(9) In the counter-affidavit filed on behalf of respondent No.2 it is pleaded that: (i) the tube rings manufactured by the petitioner company are not in conformity with IS: 13009 inasmuch as these have not been subjected to clinical trials; (ii) even under the existing Indian standards clinical trials are mandatory; (iii) the provision regarding clinical trial in clause 4.4 of the his guidelines has been wrongly deleted, presumably to avoid its repetition on the assumption that clinical trials were now required under the Drugs and Cosmetics Act, 1940 (for short the Act) and the Rules made thereunder; (iv) the Act and the Rules made there under do not make it mandatory that all samples are to be tested at Cdl and mutual agreement could provide for re-testing in a reputed independent laboratory, which has been done in the case of respondent No.2 and (v) the alleged failing in the test results conducted by the Cdl (IIT) was a deliberate attempt by the individuals concerned in Iit to unduly promote the product of the petitioners.

(10) We have heard learned counsel for the parties at length and have also perused the relevant records.

(11) As a means to control the rising population different methods of contraception are used under National Family Welfare Programme. These fall under two categories, i.e., terminal methods and spacing methods. Under the

terminal methods, with which we are presently concerned, fluoroscopic sterilisation is one of the more popular means of female sterilisation in which a pair of rings are used to block the tubes which carry egg from the ovary to uterus, the site where the feet us grows. These rings have been named as tube rings. The success of this operation depends mainly on the quality of the tube rings used for this purpose. Any cracking/breakage/slippage of the rings would result in failure of the operation leading to pregnancy. Once inserted these rings remain in the body of the woman for the rest of her life, thus increasing the necessity for using tube rings conforming to requisite standards.

(12) The tube rings have been in use in India for the last about 15 years in the National Family Welfare Programme. Before 1986-87 these were imported from abroad. Some lime in the year 1986-87, steps were initiated by respondent No.1 to standardise the specifications for tube rings, which culminated in the formulation of IS: 13009 in the year 1990 by BIS.

(13) Some of the specifications so enumerated, material for resolving the controversy in hand, arc as follows:

3.MATERIAL

3.1The tube rings shall be made from silicone rubber of medical grade which shall pass the extra tables test according to the method given in Ann.A.

4.REQUIREMENTS

4.1The tube rings shall be cut at right angle (maximum 5 angulation allowed) and shall be round without any fibrous protrusions at the outer and inner surfaces.

4.2The silicone rubber tube of which the tube ring is made shall not degrade by prolonged exposure to the biological environment or by procedure of sterilization; shall be sufficiently resistant to unintended influence by the body fluids and tissues and shall be biologically compatible without causing allergic, toxic or inflammatory reaction.

4.3The tube ring shall pass the implantation test as per the requirement of:5.1.

4.4tube ring when loaded on the fallopian tube shall produce an acceptable level of efficacy and minimal incidence of adverse reactions. The tube rings shall have undergone clinical trials approved by the Indian Council of Medical Research,

4.5The tube ring shall be radio opaque.

4.6The tube ring shall meet the requirements for stress properties as per 5.2 and 5.3 and when loaded on the fallopian tube shall have necessary memory for its inner diameter to compress the fallopian tube."

(14) To review various aspects with regard to procurement of tube rings, a joint meeting of the representatives of the Ministry of Health, the Drug Controller of India, the Indian Institute of Technology, Delhi and the manufacturers of tube

rings was organized some time in February/March 1992 and it appears from the minutes of the meeting, placed on record by the petitioners as Annexure P.7, that broad decisions taken were: (i) in view of the finalisation of the Indian standards, the Ministry will purchase only those tube rings which meet Indian standards; (ii) preference will be given to indigenous products; (iii) as per the decision of the Technical Expert Committee of the Ministry of Health and Family Welfare, the requirement of clinical trial by the Indian Council of Medical Research (ICMR) be waived off if the product is found suitable on evaluation by the Cdl, namely, the Iit, Delhi; (iv) irrespective of the source of products, from within India or abroad, tube rings which meet Indian standards will only be procured for the National Family Welfare Programmes and (v) procedure for purchase was specified and was to be the same for all products whether from abroad or India.

(15) The device tube rings was also notified as a drug under the Act, by notification dated 24 March 1993.

(16) Presumably in the light of the deliberations/guidelines, noticed above, the requirement of clinical trial, as stipulated in clause 4.4 of the his standards was dispensed with by virtue of a notification published in November 1994, whereby the above highlighted portion of clause 4.4 stood deleted.

(17) In order to decide whether and what relief can be granted to the petitioners the following questions would arise for consideration:

I)Whether the tube rings manufactured by the petitioners are to be subjected to clinical trials before they can be certified as conforming to bids standard, IS: 13009?

II)Whether as a matter of fact there was any representation or assurance held out by respondent No.1 to the petitioners as a result whereof they have altered their position by establishing the petitioner company?

III)Assuming that there was a representation, whether the plea of promissory estoppel is available to the petitioners? And

IV)Assuming that the petitioners are entitled to a mandamus, in what form can the mandamus be issued considering the special and sensitive nature of the product involved?

(18) Before we consider the afore noted questions in the light of the rival submissions, based on their pleadings and the records produced before us by learned counsel for respondent No.l, we may at this stage make a reference to the relevant provisions of the Act and the Rules made thereunder.

(19) The Act, as stated in the preamble, has been enacted to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The object of the Act was again reiterated in the Amending Act 68 of 1982 while imposing more stringent penal-ties on the anti-social elements indulging in the

manufacture or sale of adulterated or spurious drugs or drugs not of standard quality. By the said Amending Act the definition of the expression "drug" was expanded to enable control being exercised over the components of drugs and also devices which are intended for internal or external use in the diagnosis or treatment of diseases in human beings. Section 3(b) of the Act gives an inclusive definition of the expression "drug" which, inter alia, includes such substances (other than food) intended to affect the structure or any function of the human body or ..... as may be specified from time to time by the Central Government by notification in the official gazette. As noted above, the tube rings have been notified as a drug. Section 6 of the Act provides for establishment of a Central Drugs Laboratory to carry out the functions entrusted to it by the Act or any rules made under Chapter Ii of the Act.

(20) Rule 3 of the Drugs and Cosmetics Rules, 1945 prescribes the functions of the Central Drugs Laboratory. Under the said Rule, function of the laboratory is to analyze or test such samples of drugs as may be sent to it under sub-section (2) of Section Ii or under sub-section (4) of Section 25 of the Act and to carry out such other duties as may be entrusted to it by the Central Government. Sub-rule (5) of Rule 3-A of the said Rules provides that the functions of the laboratory in respect of Intra Uterine Devices and Felipe Rings shall be carried out at the Department of Biomedical Engineering of the Indian Institute of Technology, New Delhi and the functions of the Director in respect of the said device shall be exercised by the head of the said Department. Rule 122-E defines a "new drug". Since the main contention of the respondents is that the product of the petitioners is a new drug and as such cannot be purchased for distribution because it has not been subjected to clinical trials, as stipulated in Rule 122-E of the said Rules, it would be appropriate at this stage to make a reference to Rule 122-E, which reads as follows:

"122-E.Definition of new drug. - For the purpose of this part, new drug shall mean and include:

(A)A new substance of Chemical, dialogical or biotechnological origin; in bulk or prepared dosage form; used for prevention, diagnosis, or treatment of disease in man or animal; which, except during local clinical trials, has not been used in the country to any significant extent; and which, except during local clinical trials, has not been recognised in the country as effective and safe for the proposed claims.

(B)A drug already approved by the Licensing Authority mentioned in Rule 21 for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration.

(C)A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is

proposed to be changed, with certain claims, viz., indications, dosage, dosage form (including sustained release dosage form) and route of administration. (See items (b) and (c) of Appendix Vi to Schedule Y).

Explanation : For the purpose of this rule:

(I)all vaccines Shall be new drugs unless certified otherwise by the Licensing Authority under Rule 21;

(II)a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia whichever is earlier"

f (21) From a bare reading-of the aforesaid Rule it is clear that a "new drug" shall mean and include a new substance of Chemical in bulk or prepared dosage form, used for prevention, diagnosis or treatment of disease in man, which, except during local clinical trials has not been recognised in the country as effective and safe for the proposed claims. In the first instance tube rings are not used for either prevention or diagnosis or treatment of a disease in man or animal and Therefore cannot ex facie fall within the ambit of Rule 122-E, but, what if, on a liberal construction of the definition Rule, it is treated as a "new drug"? Admittedly, the tube rings have been in extensive use in the country for over a decade. Such significant user would again take it out of the ambit of the expression "new drug" as defined in Rule 122-E. The ultimate product being tube ring used for the same purpose as the imported one were being used, we feel, the mere fact of its being manufactured in India, when earlier it was imported, does not change its character and make it a new drug within the meaning of the said Rule. If on a clear reading of the said Rule the product of the petitioners does not fall within the ambit of the definition of new drug, as a necessary corollary it would also not require clinical trials, as is sought to be read in the said Rule. Therefore, in our view there is no substance in the stand of the respondents that the tube rings manufactured by the petitioners is a "new drug" within the meaning of Rule 122-E, requiring clinical trials. Except for the said Rule and the his standards, no other provision of law has been brought to our notice wherein there is either a requirement or a reference to clinical trials for a drug before it is permitted to be marketed.

(22) As regards the his standard IS:13009, as noted above, the said standard did initially provide that tube rings shall have to undergo clinical trials approved by the Indian Council of Medical Research but this requirement of clinical trial, was subsequently waived off when clause 4.4 was amended vide notification published in November 1994. Thus, in any case, from November 1994 as per the his standard IS:13009: 1990 also the tube ring is not required to be subjected to clinical trials before it is certified as conforming to the specified standard.

(23) We do not find any force in the arguments of learned counsel for respondent No.1 that unless the modifications in the his specifications are gazetted, these cannot be given effect to. Rule 125 of the said Rules provides that the standards

for mechanical contraception shall be such as are laid down in Schedule R thereto. Annexure V to Schedule R reads as under:

2.Standards for Contraceptive tube Ring (IS 13009: 1990 - Udc 615.472.6: 611.656) Contraceptive Devices tube Ring shall conform to the Indian Standards laid down from time to time by the Bureau of Indian Standards",

(24) The expression "laid down from time to time" as appearing in the afore-quoted annexure, inserted by Gazette Notification dated 24 March 1993 w.e.f. 24.3.1993, signifies that the standard for contra- ceptive tube ring has to conform to the Indian Standards laid down from time to time by the his and it is not necessary that each and every modification in the standards by his needs to be gazetted to make it enforceable.

(25) In our opinion, Therefore, the contention urged on behalf of the respondents that even after the amendment of clause 4.4 of his Standard IS: 13009 in November 1994, the tube rings manufactured or assembled in India have to undergo clinical trials, approved by Icmr, notwithstanding the fact that they have passed all the laboratory tests as per his standards, is untenable and the decision of respondent No.1 to reject petitioners'' product only on that count and to purchase the product of respondent No.2, which has also not undergone clinical trials at any stage, is not only un-reasonable and irrational but also arbitrary.

(26) Support is lent to this view by the minutes of the meeting of medical experts held on 15 December 1994, i.e., after amendment in clause 4.4 of the his standards, to discuss the issue of clinical trials for the indigenously produced tube rings, filed as annexure P-27. The material portion thereof reads as under:

".....Though indigenous manufacturers started manufacturing Cut some time back, manufacture of tube rings has been taken up only recently and their product has been tested at IIT. The original silicon Silastic tubing required for the manufacture of tube rings is still being imported and only cutting/packing and sterilisation of the cut rings is being undertaken locally.

THE question regarding considering these indigenously manufactured rings as a new drug as per the Drugs and Cosmetics Act of 1940 and the need to undertake clinical trials with the same was discussed at length and following decisions were taken:

1)Only post marketing surveillance with the indigenous rings on a minimum of 100 cases needs to be undertaken at 3 to 4 centres. Preliminary report regarding its efficacy would be ascertained by hysterosal pingography in 10% of these cases after 3 months of sterilisation and the report submitted to this Ministry. The cases would, however, be followed up for pregnancy outcome for a period of 12 to 15 months. This study is to be initiated at 4 centres of Coe e.g. Punjab/ West Bengal in the North, Delhi, Bombay and Andhra Pradesh.

2)Dr. H.H.Simon, Director, Nephew will prepare necessary protocol in

consultation with the Drug Controller of India and submit the same to this Ministry within a fortnight. The same protocol will be used by all the institutions participating in PMS."

(27) From the above it is evident that being conscious of the amendment in clause 4.4 of the his standards, the experts recommended that the indigenous rings be subjected only to Post Marketing Surveillance (PMS), meaning thereby that the experts committee also felt that there was no need for clinical trials for the indigenously produced rings, as is sought to be now pleaded on behalf of respondent No.l. Had the requirement of clinical trials been mandatory either under the Act or the his standards, the expert Committee could not substitute it only with Post Marketing Surveillance.

(28) During the course of arguments, Mr. Rakesh Tikku, learned counsel for respondent No.l, while candidly conceding that the rings produced by the petitioners may not require clinical trials, stated before us that the said respondent is willing to consider the product of the petitioners without insisting on the clinical trials provided they satisfy the Drug Controller of India that the raw-material used for production of rings is the same and acquired from the same source, namely M/s Dow Corning Corporation , Usa, as in the case of respondent No.2.

(29) Mr. S.K-Kaul, learned counsel for the petitioners, though maintained that the source of raw- material was immaterial inasmuch as it has only to conform to the standards laid down in clause 3.1 of the his standards namely " silicone rubber of medical grade which shall pass the extractable test according to the method given in Annexure A", reluctantly accepted the offer and stated that the petitioners will try to satisfy the Drug Controller that the source of their raw-material is also Dow Corning. Accordingly the Drug. Controller was asked to afford personal hearing to the petitioners for the said purpose and furnish a report in that behalf.

(30) In response thereto, the Drug Controller has filed his report wherein, while observing that there is some difference with regard to the standards of silastic medical tubing which was purported to have been supplied by M/s Dow Corning Corporation to M/s Mpc Systems Inc, Usa (who in turn had supplied tube rings to the petitioners made out of silastic tubing) and that of the standards of silastic medical grade tubing supplied by M/s Dow Corning to respondent No.2, he has finally concluded that it is only after the Fda, Usa certifies that the tube rings supplied by M/s Mps Systems, Usa to the petitioners is suitable for use as "tube ring" that "he may consider agreeing in waiving further clinical trials and would stick to his earlier opinion of approving the product with a condition that such tube rings be subjected to Pms, i.e., Post Marketing Surveillance". Although the report of the Drug Controller does not resolve the controversy, as it docs not pointedly say that no clinical trials of the product would be necessary, but it docs tend to repudiate the stand of the respondents that clinical trials of tube rings arc mandatory before these are approved for use. As a matter of fact it is evident

from the report that the only objection to the approval of petitioners'' product is the doubt about the quality of the raw-material used by them and not that it has not been subjected to clinical trials.

(31) Thus having come to the conclusion that neither under the Act or the Rules made there under nor under the his standards, presently in vogue, clinical trials is a pre-requisite parameter, for grant of approval of tube ring for use, the next question which requires consideration is whether a mandamus be straight away issued to respondent No.1 to accept the product of the petitioners on the strength of the approval granted by the Cdl (IIT) in March 1994. We feel that having regard to the nature of the device, it is neither possible nor desirable for us to make an evaluation of the product of the petitioners and of respondent No.2. In our view evaluation in technical matters, like the present one is required and should be done by the expert body, established u/s 6 of the Act, namely ,the CDL. Accordingly we direct the Director, Department of Biomedical Engineering of the Indian Institute of Technology, New Delhi, nominated under Rule 3-A(5) of the Drugs and Cosmetics Rules, 1945 to carry out the functions of the Cdl, to test the tube rings manufactured by the petitioners and respondent No.2, to evaluate as to whether they conform to the existing bids standard IS: 13009. Both the parties will be at liberty to produce any fresh material in support of their claims, which would be taken into account by the Director while considering the matter. If the said authority comes to the conclusion that the samples submitted by the petitioners and respondent No.2 do conform to the said standard, respondent No.1 shall consider for purchase and distribution under the National Family Welfare Programme, the tube rings manufactured/produced by both the parties. They will of course be at liberty to subject these supplies to post marketing surveillance as suggested by the Committee of experts in their meeting held on 15 December 1994.

(32) For the view we have taken above it is unnecessary to adjudicate upon the question as to whether there was any representation held out by respondent No.1 to the petitioners, as a result whereof they altered their position and if so, its effect:

(33) The writ petition is accordingly allowed with the aforenoted directions and the Rule is made absolute to that extent. Interim orders, directing respondent No.1 not to distribute the goods supplied by respondent No.2, if they do not conform to his standard IS: 13009: 1990, shall continue till the report in terms of this judgment is submitted by the Director, Iit, and a decision thereon is taken by respondent No.l. There will, however, be no order as to costs.

