

Shree Pacetronix Ltd. Vs. Controller of Stores and ors.

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Court : Chennai

Decided On : Apr-18-2012

Judge : K.Chandru, J.

Acts : [Constitution of India](#) - Articles 226

Appeal No. : W.P.No.9100 of 2012

Appellant : Shree Pacetronix Ltd.

Respondent : Controller of Stores and ors.

Advocate for Def. : Mr.Vellaichamy, Adv

Advocate for Pet/Ap. : Ms.S.Thenmozhi, Adv

Judgement :

This writ petition is preferred under Article 226 of the [Constitution of India](#) praying for the issue of a writ of certiorarified mandamus to call for the records of Tender Notice bearing reference No.6/12/OT/5010 issued by respondent No.1 and quash the same insofar as it seeks approval by USFDA for intended clinical use in USA for supply of Dual Chamber Pacemaker (for short DDD) and direct the respondents to consider the petitioner's offer fairly for supply of Dual Chamber Pacemaker with CE or / DGCI certification / approval instead of approval by USFDA for intended clinical use in USA.

ORDER

1. The writ petition is filed by the petitioner Company seeking to challenge the Notice Inviting Tender issued by the first respondent, i.e., Controller of Stores, Southern Railway, Chennai and to set aside the condition insofar as it seeks approval by USFDA for intended clinical use in USA for supply of Dual Chamber Pacemaker (for short DDD) and for direction to respondents to consider the petitioner's offer for supply of Dual Chamber Pacemaker with CE or DGCI certification/ approval instead of approval by USFDA for intended clinical use in USA and pass further orders.

2. When the matter came up on 4.4.2012, this court directed notice to be served on the Standing Counsel for the Southern Railway Mr.M.Vellaisamy. Accordingly, the Standing Counsel was served. He also entered appearance and has filed a counter affidavit on behalf of respondents sworn to by the third respondent, dated 16.4.2012.

3. The case of the petitioner was that the first respondent had issued a Notice Inviting Tender. The petitioner company had purchased a copy of the tender schedule. The tender is for Dual Chamber Pacemaker for supply to the Railway hospital, Perambur as per the specifications enclosed. The petitioner was aggrieved by the condition specified therein which is as follows:

"Should be approved by the US FDA for intended clinical use in USA."

4. The contention of the petitioner was that though Pacemakers should have USFDA / CE certification, the further qualification that it should be for intended clinical use in USA was to exclude the pacemakers with CE certification from the zone of consideration. They virtually in the name of specifications had amended the original requirements. There are various Central Government organisations, such as All India Institute of Medical Sciences (for short AIIMS), G.B. Pant Hospital and Eastern Railway have invited tenders for pacemaker, wherein the condition was that pacemaker must be USFDA / equivalent European certification (CE) / DGCI Indian approved. For the first time, a departure has been made with a view to eliminate the competition and to favour few international manufacturers

who have USFDA certification. The condition imposed was an arbitrary condition. The petitioner company has licence from the Government of India for manufacture of cardiac pacemaker. The petitioner company has also got ISO certification as well as European certification on 12.1.2010. Thus the company has both Indian as well as European certification relating to quality of pacemaker. If any comparison is found between the USFDA and European certification, then the CE certification is more stringent and products certified by the CE certification are better than the USFDA certified products. Apart from comparison, the petitioner company had collected views of medical experts who have certified that both certifications have same scope. The company also got orders from Dr. Ram Manohar Lohia Hospital, New Delhi and JIPMER, Pondicherry, etc. The company could not apply for tender because of the arbitrary condition imposed by the respondents. Under these circumstances, the writ petition came to be filed.

5. In the counter affidavit filed by the respondents, it was indicated that the condition imposed did not eliminate any competition. Already there are six pacemaker companies with USFDA certification, i.e., Medtronic, Boston Scientific, St. Jude Medical, Vitatron, Biotronik and Sorin. These companies are market leaders and were responsible for 95% of the market shares. This will show the confidence of the medical community in their products. The condition imposed by the railways ensures the competition in the tender between the world leaders who make quality pacemakers. The fact that some Indian manufactures do not have US FDA certification does not have any particular relevance as the Railways are intended to get the best global products for the benefit of critically ill cardiac patients. They cannot leave the selection only to Indian companies. The pacemakers are highly technology devises on which patients life depends. Therefore, the railway was intended to get best possible products in the World. The railways have got their own right to define their own criteria for product selection keeping in mind such criteria to ensure that all leading manufactures and distributors of a particular product who are recognised worldwide and who satisfy stringent norms for device quality and patient safety can participate in the tender.

6. It was further stated that the decision was made by the railways with due application of mind by a competent technical authority nominated by the Chief

Medical Director of Southern Railway. The specifications were counter signed by the senior and responsible officers of the Railway Hospital, Perambur, the Medical Director and the Chief Medical Director of Southern Railway. The USFDA certification is based on the product quality and clinical data. The USA had imposed stringent conditions. They are recognised to be the highest in a given field. Even many products which have CE certification are only few with global leaders. In the past, on several occasions the Railways had rejected products which have only CE certification on technical grounds. There was no truth in the charge of arbitrariness and there was no favoritism. The railways were guided by the public interest. It was also contended that any interdiction of railway's efforts to get best quality products would jeopardize the interest of critically serious cardiac patients.

7. Ms.S.Thenmozhi, learned counsel for the petitioner referred to a judgment of the Supreme Court in Reliance Energy Ltd. and another Vs. Maharashtra State Road Development Corporation Ltd. and others reported in (2007) 8 SCC 1 for contending that Articles 14, 21 and 19(1)(g) ensures that the Government contracts must have level playing field to all bidders and that the norms and benchmarks must have clarity so as to ensure legal certainty, which must satisfy the test of reasonableness and that any discriminatory treatment will violate the doctrine of level playing field.

8. However, this court is not persuaded to accept the contentions of the learned counsel for the petitioner. It is open to the authority to specify the conditions for their products to ensure the quality of product. As rightly contended, it was not intended to save either one supplier or the company. The averments in the counter affidavit are not denied by way of filing any rejoinder.

9. With reference to the purchase of medical equipments and products and the magnitude, complexity and technical nature involved and in view of far-reaching implications, the Supreme Court vide its judgment in Vincent Panikurlangara v. Union of India reported in (1987) 2 SCC 165 held that in such matters, maintenance of quality is important and the judicial proceedings is not an appropriate one. In paragraphs 15,18 and 21, the Supreme Court had observed as

follows:

"15. Having regard to the magnitude, complexity and technical nature of the enquiry involved in the matter and keeping in view the far-reaching implications of the total ban of certain medicines for which the petitioner has prayed, we must at the outset clearly indicate that a judicial proceeding of the nature initiated is not an appropriate one for determination of such matters.

18. The branch with which we are now dealing, namely, health care of citizens, is a problem with various facets. It involves an ever-changing challenge. There appears to be, as it were, a constant competition between Nature (which can be said to be responsible for new ailments) on one side and human ingenuity engaged in research and finding out curative processes. This being the situation, the problem has an ever-shifting base. It is commonplace that what is considered to be the best medicine today for treatment of a particular disease becomes out of date and soon goes out of the market with the discovery or invention of new drugs. Again what is considered to be incurable at any given point of time becomes subjected to treatment and cure with new finds. There is yet another situation which must be taken note of as human knowledge expands and marches ahead. With the onward march of science and complexities of the living process hitherto unknown diseases are noticed. To meet new challenges, new drugs have to be found. In this field, therefore, change appears to be the rule.

21. The prescribed preparations must maintain their quality, and for ensuring it, strict regulations are necessary. Provision in statutes or rules or instructions issued by executive authorities do not meet the demands of today's situation. The process of regulation has to be strengthened. Law must be provided with sufficient biting teeth and there must be genuine apprehension in the mind of every person engaged in the trade that any infraction would be visited with exemplary punishment. In the prevailing situation in the country, unless the law is properly enforced, it would be difficult to regulate the quality of the drugs. Standardisation of the preparations will also introduce a healthy atmosphere in the market. The practising doctor should be acquainted with the drug policy, availability of drugs and take care to prescribe available medicine to his patient."

10. The further scope and ambit of judicial review over the condition imposed in the notice inviting tender is also set out by the Supreme Court in *Union of India v. Hindustan Development Corpn.*, reported in (1993) 3 SCC 499. It is necessary to extract the following passages found in paragraphs 7,27,28 and 33, which reads as follows:

"7.It is true, as it is today, that the Government in a welfare State has wide powers in regulating and dispensing of special services like leases, licences, and contracts etc. The magnitude and range of such Governmental function is great. The Government while entering into contracts or issuing quotas is expected not to act like a private individual but should act in conformity with certain healthy standards and norms. Such actions should not be arbitrary, irrational or irrelevant. In the matter of awarding contracts inviting tenders is considered to be one of the fair ways. If there are any reservations or restrictions then they should not be arbitrary and must be justifiable on the basis of some policy or valid principles which by themselves are reasonable and not discriminatory.....

27. Of late the doctrine of legitimate expectation is being pressed into service in many cases particularly in contractual sphere while canvassing the implications underlying the administrative law. Since we have not come across any pronouncement of this Court on this subject explaining the meaning and scope of the doctrine of legitimate expectation, we would like to examine the same a little more elaborately at this stage. Who is the expectant and what is the nature of the expectation? When does such an expectation become a legitimate one and what is the foundation for the same? What are the duties of the administrative authorities while taking a decision in cases attracting the doctrine of legitimate expectation.

28. Time is a three-fold present: the present as we experience it, the past as a present memory and future as a present expectation. For legal purposes, the expectation cannot be the same as anticipation. It is different from a wish, a desire or a hope nor can it amount to a claim or demand on the ground of a right. However earnest and sincere a wish, a desire or a hope may be and however confidently one may look to them to be fulfilled, they by themselves cannot amount

to an assertable expectation and a mere disappointment does not attract legal consequences. A pious hope even leading to a moral obligation cannot amount to a legitimate expectation. The legitimacy of an expectation can be inferred only if it is founded on the sanction of law or custom or an established procedure followed in regular and natural sequence. Again it is distinguishable from a genuine expectation. Such expectation should be justifiably legitimate and protectable. Every such legitimate expectation does not by itself fructify into a right and therefore it does not amount to a right in the conventional sense.

33..... The protection is limited to that extent and a judicial review can be within those limits. But as discussed above a person who bases his claim on the doctrine of legitimate expectation, in the first instance, must satisfy that there is a foundation and thus has locus standi to make such a claim. In considering the same several factors which give rise to such legitimate expectation must be present. The decision taken by the authority must be found to be arbitrary, unreasonable and not taken in public interest. If it is a question of policy, even by way of change of old policy, the courts cannot interfere with a decision. In a given case whether there are such facts and circumstances giving rise to a legitimate expectation, it would primarily be a question of fact. If these tests are satisfied and if the court is satisfied that a case of legitimate expectation is made out then the next question would be whether failure to give an opportunity of hearing before the decision affecting such legitimate expectation is taken, has resulted in failure of justice and whether on that ground the decision should be quashed. If that be so then what should be the relief is again a matter which depends on several factors."

11. Similar view was expressed by the Supreme Court in *Nagar Nigam v. Al Faheem Meat Exports (P) Ltd.*, reported in (2006) 13 SCC 382 and in paragraphs 21 to 23 it was observed as follows:

"21. In the present case, Respondent 1 challenged the impugned advertisement dated 6-12-2004 issued by the Nagar Nigam. We have carefully perused the said advertisement and find no illegality in the same. It has been held by this Court in several decisions that the court should not ordinarily interfere with the terms mentioned in such an advertisement. Thus in *Global Energy Ltd. v. Adani Exports*

Ltd.¹⁰ this Court observed (vide SCC p. 441, para 10):

10. The principle is, therefore, well settled that the terms of the invitation to tender are not open to judicial scrutiny and the courts cannot whittle down the terms of the tender as they are in the realm of contract unless they are wholly arbitrary, discriminatory or actuated by malice.

22. Similarly, in *Master Marine Services (P) Ltd. v. Metcalfe & Hodgkinson (P) Ltd.*¹¹ this Court held that the modern trend points to judicial restraint in reviewing the administrative action. The court does not sit as a court of appeal over such a decision but merely reviews the manner in which the decision was made. The court ordinarily would not interfere with an administrative decision. The Government must have freedom of contract. Some fair play in the joints is a necessary concomitant for an administrative body functioning in an administrative sphere.

23. We have carefully perused the impugned advertisement and we do not find any arbitrariness, discrimination or mala fides in the same. Hence the High Court had no justification for interfering with the said advertisement."

12. In view of the above factual matrix and the legal precedents set out, it is not a fit case where any relief can be granted to the petitioner. Hence the writ petition will stand dismissed. No costs.

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