(2019) 11 GAU CK 0032

In the Gauhati High Court

Case No : Writ Petition (C) No. 4883 Of 2019

Ridley Life Science Pvt. Ltd. APPELLANT

Vs

State Of Assam And Anr RESPONDENT

Date of Decision : 14-11-2019

Acts Referred:
Drugs And Cosmetics Rules, 1945 — Rule 68, 71, 71(7), 71(A), 74, 76, 78, 85
Constitution Of India, 1950 — Article 14, 19(1)(g), 226

Citation : (2019) 11 GAU CK 0032

Hon'ble Judges : Suman Shyam, J

Bench : Single Bench

Advocate : D Hussain

Final Decision : Dismissed

Judgement

1. Heard Mr. Sumit Rajput, learned counsel appearing on behalf of the writ petitioner. I have also heard Mr. D. Saikia, learned senior counsel assisted

by Mr. B. Gogoi, learned Standing Counsel, Health Department, Assam, appearing for the respondents.

2. The writ petitioner herein is a private limited company having its corporate office at Narela, New Delhi. Aggrieved by insertion of Clauses- 2.3.1

and 2.5.1 in the NIT dated 05.07.2019 issued by the respondent No.2 inviting Online tenders for supply of essential drugs to health facilities under the

department of Health and Family Welfare, Government of Assam, for a period of two years, the present writ petition has been filed.

3. The case of the writ petitioner, in a nutshell, is that, it is a manufacturer of pharmaceutical drugs and is holding Drug Manufacturing Licence

No.1930/1931 issued under the Drugs and Cosmetics Act, 1940. The petitioner is also holding a valid â??GMPâ? and â??GLPâ? certificate as well

as no â??conviction certificateâ?issued by the competent authority and therefore, is competent to manufacture and market pharmaceutical products.

The writ petitioner was interested to participate in the tender process initiated by the NIT dated 05.07.2019. However, due to the insertion of clauses

Clauses-2.3.1 and 2.5.1 in NIT the petitioner has been rendered in-eligible to participate in the tender. Hence, this writ petition for quashing the

aforementioned eligibility clauses contained in the tender.

4. Clause 2.3.1 provides that the bidder must have three years market standing of the items quoted in the bid. As per Clause 2.5.1 a valid WHO-GMP

certificate issued by the appropriate licensing authority not older than one year from the date of submission of the bid is an essential condition for the

bidders to participate in the bidding process. The writ petitioner herein, admittedly, does not hold a WHO-GMP Certificate and therefore, did not meet

the eligibility condition prescribed under the NIT. The petitionerâ??s case is that clauses 2.3.1 and 2.5.1 have been deliberately inserted in the NIT so

as to extend undue favour to a chosen few.

5. By placing heavy reliance on an un-reported judgment of the Jammu and Kashmir High Court in the case of Rohit Drugs and others Vs. State and

others (decided on 04.03.2002) and another decision of the High Court of Judicature at Uttaranchal in the case of Poddar Pharmaceutical Ltd. &

others Vs. State of Uttaranchal and others(decided on 24.05.2003) Mr. Rajput has argued that in both the aforementioned decisions it has been

categorically held that â??WHO-GMPâ? certificate is required only by the firms who intend to export the medicines and therefore, there is no

requirement for a manufacturer to hold such a certificate for the purpose of domestic supplies. By producing a copy of the order passed by the

Honâ??ble Supreme Court dismissing the SLP preferred against the aforesaid decision of the Uttaranchal High Court ,Mr. Rajput has argued that

the decision of the Uttaranchal High Court having been affirmed by the Supreme Court, law is now settled that a â??WHO-GMPâ? certificate is not

required for a domestic supplier.

6. By referring to a circular issued by the Drug Controller General of India dated 01.03.2009 whereby, all the State Drug Controllers have been asked

not to entertain request for issuing of WHO-GMP certificate by the manufacturers of pharmaceuticals products to supply in India, Mr. Rajput has

emphatically argued that a domestic drug supplier would not be entitled to even apply for a â??WHO-GMPâ? Certificate and if there is any doubt on

the aforesaid issue, the same stood resolved in favour of his client due to the contents of the circular dated 01.03.2009.

7. By relying upon another unreported decision of the High Court of Judicature at Hyderabad in the case of Bharat Biotech International Limited and

others Vs. A.P. Health and Medical Housing and Infrastructure Development Corporation and others (decided on 10.12.2002), Mr. Rajput has argued

that insistence onâ??WHOâ? pre-qualification for supply of drugs by the domestic manufacturers has been held to be arbitrary and violative of

Articles 14 and 19(1)(g) of the Constitution of India. That apart, the learned counsel for the petitioner, has also argued that since the drugs

manufactured by his client is available in the open market based on the licence issued under the provisions of the Drugs and Cosmetics Act, 1940 as

well as the Rules framed thereunder and no Governmental agency has prohibited such drugs, the insistence on the three years market experience as

eligibility condition to participate in the bidding process is ex-facie arbitrary and illegal. On the basis of the aforementioned submissions the learned

counsel for the petitioner has prayed for striking down Clauses-2.3.1 and 2.5.1 of the NIT and for issuance of a writ of mandamus directing the

respondents to allow his client to participate in the bidding process.

8. Mr. D. Saikia, learned senior counsel appearing for the respondents, on the other hand, has strongly opposed the prayer made in the writ petition by

questioning the locus standi of the writ petitioner to approach this Court by filing the present petition. According to Mr. Saikia, the writ petitioner had

neither sought leave of this Court to participate in the tender process nor did it possess a valid GMP certificate on the last date of submission of the

bids. Notwithstanding the same, the present writ petition has been filed only to obstruct the tender process for purposes other than bona fide. By

referring to the averments made in the counter-affidavit filed by the respondent No.2, Mr. Saikia submits that the impugned clauses have been

inserted in the NIT on the basis of a conscious policy decision of the State Government with a view to ensure that better quality of medicines are

supplied in the government hospitals. Contending that 73 bidders including a number of SSI and MSME units as well as individual bidders, who meet

the eligibility conditions, have already submitted their bids, the learned senior counsel submits that no case of arbitrariness or malafide exercise of

power by the State Government has been made out warranting interference by this Court in the tender process. In support of his above arguments,

Mr. Saikia has also drawn the attention of this Court to the series of NITs floated by the various State Governments as well as the Central

Government agencies in the recent time which includes similar eligibility conditions to contend that stringent quality control measures in supply of

medicines is the need of the day.

9. By referring to a decision rendered by the Madhya Pradesh High Court in the case of Association of Industries, Madhya Pradesh Vs. State of

M.P. reported in 2013 SCC Online MP 5776 Mr. Saikia has argued that challenge made by the association of drug manufacturers of that State to a

similar condition in the tender floated for supply of medicine in the Government Hospitals in the form of condition No.(j) was rejected by the court by

holding that insisting on such condition was permissible. By referring to two decisions of the Supreme Court rendered in the case of Directorate of

Education and others Vs. Educomp Datamatics Ltd. and others reported in (2004) 4 SCC 1 9and in the case of Michigan Rubber (India) Limited Vs.

State of Karnataka and others reported in (2012) 8 SCC 216 Mr. Saikia has further argued that the State must be permitted free hand in deciding the

terms and conditions of tender and unless the policy decision of the State is found to be arbitrary, discriminatory or actuated by malice, the writ court

would not interfere with such a decision.

10. I have considered the submissions made by learned counsel for both the parties and have meticulously gone through the materials brought on

record.

11. Since the controversy arising in this proceeding revolves around Clauses-2.3.1 and 2.5.1 of the NIT dated 05.07.2019, both the aforesaid clauses

are extracted herein below for ready reference :-

â??2.3.1. Bidder should have at least 3 yearsâ?? market standing as a manufacturer for the items quoted in the bid, as on the date of bid

opening. In the case of imported products, the product should have minimum 3 years standing in the market. The importer should have at

least 3 years standing as manufacturer/importer of drugs in general. Market

standing of the product will be obtained from Competent

Authority like Drug Control Deptt.â??

â??2.5.1. Manufacturer of the drugs should hold a valid WHO-GMP certificate issued by the appropriate Licensing Authority. The WHO-

GMP certificate must not be older than one year from the date of bid submission in the case where validity is not mentioned in the

certificate.â??

12. Since the learned senior counsel for the respondents has assailed the maintainability of the writ petition on the ground that the writ petitioner did

not hold a valid GMP certificate on the last date of submission of the bid and therefore, in any case, was not eligible to participate in the bidding

process, the said plea is taken up for consideration first in point of time.

13. Part VII of the Drugs and Cosmetics Rules, 1945 (for short â??Rules of 1945â?) which contains Rules 68 to 85, deals with â?? Manufacture for

Sale (For Distribution) of Drugs other than Homoeopathic Medicinesâ?. Schedule-M of the Rules, which pertains to rules 71,74,76 and 78, deals with

Good Manufacturing Practice (GMP) and requirement of premises, plant and equipment for pharmaceutical products. To achieve the objective of the

Rules, each licensee is required to evolve appropriate methodology, systems and procedure for manufacturing pharmaceutical products which should

be documented and maintained for inspection and reference. Schedule-M lays down a detail guideline to be followed by the manufacturers of

pharmaceutical drugs which includes measures to be adopted for Quality Control Area.

14. Rule 71(7) of the Rules of 1945 provides that the licensee shall comply with the requirements of â??Good Manufacturing Practiceâ? as laid down

in Schedule M. Rule 71A lays down the conditions for grant or renewal of a licence in Form-B and as per sub-rule (2), compliance of conditions laid

down in Schedule M is a pre-condition for grant or renewal of such licence. From the scheme of the Rules of 1945, it is clear that the rules prescribe

stringent quality control measures to be adhered to by the manufacturers of pharmaceutical drugs. Such measures are obviously aimed at maintaining

purity and high quality of the medicines. Therefore, it is clear that as per the Rules of 1945, a valid GMP Certificate is a sine- qua-non for the

manufacturers of pharmaceutical drugs to carry out production activities.

15. While the GMP certification is prescribed under Schedule M of the Rules, there is no wrangle at the bar that the â??WHO-GMPâ? certification

pertains to international standards and therefore, relates to a higher Quality Control (QC) norm in the process of manufacturing pharmaceutical drugs.

16. It appears that the writ petitioner herein was issued a GMP certificate by the Deputy Drugs Controller, GMP, Delhi on 17.08.2017 which was

valid upto 31.05.2019. Before the expiry of the said GMP certificate the writ petitioner had submitted an application before the Deputy Drugs

Controller for renewal of the same. However, there is nothing on record to indicate that the GMP certificate issued to the petitioner was actually

renewed by the authorities beyond 31.05.2019.

17. The conditions laid down in the NIT dated 05.07.2019 categorically mentioned that the last date and time of submission of on-line bid is 30.07.2019

upto 2.00 PM. There is no dispute about the fact that under the NIT conditions, no bidder would be eligible to participate in the on-line bidding process

without a valid GMP Certificate. However, as noted above, it appears that as on the last date of submission of the bids, the writ petitioner was not

holding a valid GMP certificate. It is, therefore, apparent that even dehors the eligibility conditions under challenge in the present writ petition, the

petitioner company was not eligible to participate in the tender process. Although Mr. Rajput has argued that failure on the part of the respondent

authorities to reject the prayer for renewal of the GMP Certificate must be deemed as an automatic renewal of the certificate, in the absence of any

deeming provision in the rules providing for such a conclusion, I am unable to accept such a submission of Mr. Rajput. Therefore, this Court is of the

opinion that, not to speak of the â??WHO-GMPâ? certificate, the writ petitioner was not even holding a valid GMP certificate as per Schedule M of

the Rules and hence, was even otherwise, not eligible to participate in the tender process. As such, I find force in the submission of Mr. Saikia that the

writ petitioner did not have the locus to approach this court by filing the present petition.

18. Coming to the merit of the case, in the counter-affidavit filed by the respondents, it has been categorically mentioned that the purpose for insisting

on a WHO-GMP certificate is to ensure better quality of pharmaceutical products are made available to the Health Department for the benefit of the

public. In support of the above contention, the respondent No 2 has also mentioned the differences between a WHO-GMP and GMP Certificate

which would be relevant for the purpose of this case and therefore, is extracted herein below :-

â??The essential difference between WHO-GPMP and GMP certificate is as under :

a) Good manufacturing practices mentioned in Schedule-M of the Drug Rules in India are less stringent than WHO-GMP. WHO-GMP is in

two parts. Part-A deals with good practices in the manufacture and quality control of drugs, whereas Part-B deals with classification

scheme on the quality of pharmaceutical products moving in international commerce.

b) A distinct feature of WHO-GMP is that it is product based, whereas GMP is not so. GMP deals with physical infrastructure including

sanitation and efficient equipment, purity or raw materials and personal hygiene of the workers/ employees as well as the surroundings &

settings of the manufacturing facility.

Â Schedule-M of the Drugs & Cosmetics Rules has been amended and purports to introduce WHO-GMP in India.â??

19. In the counter-affidavit it has further been mentioned that three years market standing is necessary for the State Government to confirm the

stability data of the quoted items and to verify if successful existence of the medicine in the market conforms to the prescribed parameters as per the

Drugs and Cosmetics Act, 1940. From a bare reading of the averments made in the counter-affidavit it is clear that the idea behind Clause 2.3.1 was

to gather reliable data for a period spanning over three years on the performance of the drugs offered to be supplied by the manufacturer. The writ

petitioner, while admitting in the rejoinder affidavit that the WHO-GMP was more broad- based than the GMP, has stated that insisting on WHO-

GMP certificate would add to the cost of manufacturing thereby shifting the burden upon the patients. I am unable to agree with the said contention of

the writ petitioner firstly because there is no data available on record to indicate the cost component of a WHO-GMP pre-condition in the process of

manufacturing the medicines. Secondly, in the name of affordability, the State cannot be restrained by the court from insisting upon better quality of

medicines to be supplied to the public.

20. After the decision of the Supreme Court in Tata Cellular vs. Union of India reported in (1994) 6 SCC 651 law is firmly settled that terms of a

tender lies in the realm of the contract and the court would not sit in appeal over the decision of the tendering authorities to have a particular clause in

the contract.

21. In Air India Ltd. Vs. Cochin International Airport Ltd. reported in (2000) 2 SCC 61 7the Supreme Court has observed that award of contract by a

public body or the State is essentially a commercial transaction and the State can chose its own terms of invitation to tender which is not open to

judicial scrutiny. Following the principles laid down in the said decision, the apex court, in Monarch Infrastructure (P) Ltd. Vs. Commr., Ulhasnagar

Municipal Corpn. reported in (2000) 5 SCC 287, has observed that terms and conditions in a tender are prescribed by the government bearing in mind

the nature of contract and in such matter, the authority calling for the tender is the best judge to prescribe the conditions of tender.

22. In the case of Directorate of Education and others(supra) the Supreme Court has restated the above principles and has summed the law by

making the following observations :-

â??12. It has clearly been held in these decisions that the terms of the invitation to tender are not open to judicial scrutiny the same being

in the realm of contract. That the government must have a free hand in setting the terms of the tender. It must have reasonable play in its

joints as a necessary concomitant for an administrative body in an administrative sphere. The courts would interfere with the administrative

policy decision only if it is arbitrary, discriminatory, mala fide or actuated by bias. It is entitled to pragmatic adjustments which may be

called for by the particular circumstances. The courts cannot strike down the terms of the tender prescribed by the government because it

feels that some other terms in the tender would have been fair, wiser or logical. The courts can interfere only if the policy decision is

arbitrary, discriminatory or mala fide.â??

23. In Michigan Rubber (India) Limited (supra) the Apex Court has observed that the basic requirement of Article 14 is fairness in the action by the

State and their action would be amenable to the judicial review only to the extent that the State must act validly for a discernible reason and not

whimsically for any ulterior purpose. The Supreme Court has further observed that the Court before interfering in a tender or contractual matter in

exercise of power of judicial review should pose to itself the following questions :-

â??(i) Whether the process adopted or decision made by the authority is male fide or intended to favour someone; or whether the process

adopted or decision made is so arbitrary and irrational that the court can say: â?? the decision is such that no responsible authority acting

reasonably and in accordance with relevant law could have reachedâ??? and

(ii) Whether the public interest is affected?â??

24. Again, in the case of Central Coalfields Limited and another Vs. SLL-SML (Joint Venture Consortium) and others reported in (2016)8 SCC 622

the Apex Court has reiterated the principles laid down in Ramana Dayaram Shetty Vs. International Airport Authority of India reported in (1979) 3

SCC 489 and has observed that the terms of a document should not be treated as superfluous or redundant but must be given some meaning and

weightage. It has been held that whether a term of NIT is essential or not is a decision to be taken by the employer which should be respected. The

lawfulness of such decision of the employer can be questioned on very limited grounds but the soundness of the decision cannot be questioned

otherwise the Court would be taking over the role of tender issuing authority which it cannot.

25. From a careful analysis of the ratio laid down in the aforementioned decisions of the Supreme Court it is thus clear that in exercise of powers of

judicial review the scope of interference in a tender matter is extremely limited and the decision of the authorities can be struck down only if the same

is found to be arbitrary, discriminatory or actuated by bias. Likewise, the terms and conditions of a tender, being in the realm of contract, also would

not be open to judicial review by the court unless it is found that such conditions have been incorporated only to favour a particular person or the same

is being used with an ulterior motive and as a tool of discrimination. Therefore, the writ court, in exercise of discretionary jurisdiction under Article 226

of the Constitution of India, would be loath in interfering with the terms and conditions of a public tender for it is not for the court to decide on the

suitability of the terms on which a tender is to be invited. An exception to this rule can, however, be made out if malafide in the action of the state or

its officials is established by bringing cogent materials on record.

26. In the present case, as noted above, I find from the record that the Government of Assam, through the department of Health and Family Welfare,

has taken a conscious policy decision to ensure highest standard of the drugs/ medicines that are to be supplied to the various hospitals. There can be

hardly any doubt about the fact that the performance of the medicines can be assessed on the basis of data collected over a period of time and

therefore, insistence on three years market standing experience has a reasonable nexus with the purpose sought to be achieved. Likewise, insistence

of WHO-GMP certificate is also aimed at ensuring quality control measures and therefore, insistence on such a condition, in the facts of the case,

cannot be termed as arbitrary exercise of administrative power.

27. It is also evident from the documents available on record that as many as 73 bidders who fulfil the eligibility conditions including the â??WHO-

GMPâ? criteria, have submitted their bids and the list of such bidders have been annexed to the counter-affidavit filed by the respondent No 2. The

petitioner has not impleaded any of those bidders in this writ petitioner nor sought any relief against them. Therefore, the contention of the

petitionerâ??s counsel that Clauses 2.3.1.and 2.5.1 have been designedly inserted in the NIT only to favour selected bidders is found to be

completely baseless and hence, stands rejected. It is to be noted here-in that the core question in this case is not whether a â??WHO-GMPâ?

Certificate is required for domestic supply of medicine but as to whether the State is de-barred from insisting on such a norm in its tenders. There is

nothing in the Act or the Rules prohibiting the government from inserting such tender condition. As such, after a thread bare analysis of the pleadings

of both the parties, this court is of the opinion that no case for interference with the eligibility conditions contained in the NIT is made out.

28. In Rohit Drugs and Others (supra) relied upon by Mr. Rajput the petitioners were not allowed to participate in the Tender process since they did

not hold a WHO-GMP certificate. By observing that a licensee must be presumed to hold a GMP certificate it was held that the licensee must be

afforded a reasonable opportunity to show that the medicines manufactured by them were acceptable. Likewise, in Bharat Biotech International

Limited and Others (supra) only one manufacturer had the WHO pre-qualification

to supply Hepatitis-B vaccine and it was in such facts that the

tender condition was held to be tailor â?"made for one person. However, the legality of prescribing such attender condition was not decided in that

case. In Poddar Pharmaceutical Ltd. & others (supra), the High Court of Judicature at Uttaranchal had held that the State Government cannot

deprive the petitioner to participate in the tender for want of WHO-GMP Certificate on the ground that the said certificate was required only to export

medicines. However, the aforesaid decision does not lay down the law that the State, for good reasons, cannot insist on WHO-GMP Certificate from

the supplier of medicines in government hospitals. Therefore, the aforesaid decisions relied upon Mr. Rajput, in the opinion of this court, were rendered

in the facts and circumstances of those cases and hence, would not have any bearing in this case.

29. A perusal of the order dated 28.01.2005 passed in SLP (Civil) No 16026/2003 preferred against the decision of the High Court of Uttaranchal

goes to show that the dismissal of the SLP was not on merit but on a technical ground. What is to be noted herein that since the decision rendered by

the High Court of Uttaranchal on 24.05.2003 there have been significant changes in the horizon of drug manufacturing activities in this country and

several instances of fake/ impotent drugs have been detected to be in circulation in the market. Therefore, the administrative departments cannot be

presumed to be oblivious of such development nor can they be prevented from stepping up the vigil for ensuring better quality of medicines being

supplied to the hospitals. Moreover, ensuring high standard of medicines would be in the interest of the public in general and hence, the writ court

would not come in the way of such a process initiated by the department. The documents available on record pertaining to the recent years also

unequivocally go to show that a number of State Governments including the States of Maharashtra, Kerala, Karnataka, Gujarat and some Central

Government agencies have inserted identical eligibility clauses in similar tenders issued for supply of medicines. From the above, it is apparent that the

decision to insert the impugned conditions in the present NIT is not an isolated event but is in consonance with the practice followed across the nation.

30. In the case of Association of Industries, Madhya Pradesh (supra), a Division Bench of the High Court of Madhya Pradesh has rejected the

challenge made to clause No.(j) in the tender invited by the State which required the manufacturer to have WHO-GMP inspection certificate.

According to the petitioners, the condition No (j) was arbitrary and discriminatory. While rejecting the plea of the petitioner association, the Madhya

Pradesh High Court has held that condition (j) has nexus with the object sought to be achieved which is to ensure regular supply of quality medicine in

the Government hospitals and therefore, was valid. Rejecting a similar argument, as advanced by Mr. Rajput based on the circular dated 01.03.2009

issued by the Drug Controller General, the Division Bench has further held that it is an internal letter issued by the Drug Controller which was

advisory in nature and from the said letter, it cannot be inferred that the State is not empowered to insert a condition in the Tender relating to WHO-

GMP Certificate. I am in respectful agreement with the aforesaid observation of the Madhya Pradesh High Court.

31. For the reasons stated herein before, I am of the view that this writ petition is devoid of any merit and the same is accordingly dismissed.

There would be no order as to cost.

