

IN THE HIGH COURT AT CALCUTTA
CIVIL APPELLATE JURISDICTION
APPELLATE SIDE

BEFORE :-

THE HON'BLE JUSTICE SHAMPA SARKAR
&
THE HON'BLE JUSTICE ARJUN RAY MUKHERJEE

MAT 1717 of 2026

with
CAN 1 of 2026

**ICHOR Biologics Private Limited
vs.
The State of West Bengal & Ors.**

For the Appellant

: Mr. Jaydip Kar, Sr. Adv.,
Mr. Suman Kumar Dutt, Sr. Adv.,
Mr. Soumya Majumder, Sr. Adv.,
Mr. Paritosh Sinha, Adv.,
Mr. Amitava Mitra, Adv.,
Ms. Sumita Shaw, Adv.,
Mr. Sakabda Roy, Adv.,
Mr. Naman Agarwal, Adv.,
Ms. Shrestha Datta

For the State

: Mr. Surajit Nath Mitra, Ld. A.G.,
Mr. Billwadal Bhattacharyya, Ld. A.A.G.,
Mr. Srijib Chakraborty, Adv.,
Mr. Aditya Mondal, Adv.

For the Respondent Nos. 2

: Ms. Shiv Shankar Banerjee, Adv.,
Mr. Jatinder Singh Dhatt, Adv.

Judgment reserved on : 05.10.2026

Judgment pronounced on : 08.10.2026

Shampa Sarkar, J.

1. The appeal arises out of a judgment and order dated September 30, 2026, passed in WPA No. 20748 of 2026. By the impugned judgment,

His Lordship dismissed the writ petition, inter alia, holding that, there was no illegality on the part of the respondents in rejecting the technical bid of the appellant as the license which was renewed under Form 26(I) of the Drugs Rules 1945, had not been approved by the Central License Approving Authority, (hereinafter referred to as 'the Approving Authority'). The renewal of license granted by the State Licensing Authority (hereinafter referred to as 'the Licensing Authority') might not be approved by the Approving Authority and as such, the tendering authority rightly considered the certificate issued by the Licensing Authority to be invalid. The appellant was disqualified at the technical round only on the ground that the renewed license did not bear the stamp of approval of the Approving Authority.

2. According to His Lordship, without the approval of the Approving Authority, the respondents could not accept the license issued by the Licensing Authority. Allowing the appellant to participate in the financial bid would be de hors the eligibility criteria. His Lordship considered clause 4(a) of the eligibility criteria in the tender document and held that application for renewal and grant of renewal were two separate exercises under the law. His Lordship having considered the contents of Form 26(I) of the Drug Rules, 1945 (hereinafter referred to as the said Rules) as also, Rule 68A, Rule 81 and Rule 122F, arrived at a conclusion that the above mentioned rules provided that, apart from the satisfaction of the Licensing Authority, the applicant should also fulfil the requirements under the law for renewal. The Approving Authority was also required to be satisfied that the applicant was in a position to fulfil the statutory

obligation. The law permitted the Approving Authority to either suspend or cancel or revoke any license issued by the Licensing Authority. Participation of the appellant in the tendering process on the basis of renewal of the license by the State Licensing Authority under Form 26(I), but without the approval by the Approving Authority was contrary to the eligibility criteria prescribed by the tendering authority and as such, the rejection of the bid of the appellant in the technical round was justified.

3. Mr. Kar, learned Senior Advocate for the appellant submitted that the Licensing Authority issued the certificate of renewal of license for manufacture of blood products under Form 26(I), read with Rule 122(I) of the said Rules on June 22, 2026. Such power to renew the license was vested in the Licensing Authority by Rule 122F of the said Rules. The second proviso to Rule 122F(1) provided that the application for renewal of a license which had been issued under Form 28(E) read with Rule 68A, shall be made before expiry of the said license in the prescribed form mentioned in the Rules, and during pendency of such application, the applicant could continue to operate the centre or manufacture blood products or collect or process or test or store such product till orders on his application were communicated to him. Referring to Rule 68A, Mr. Kar submitted that a license was to be granted by the Licensing Authority as per the procedure laid down therein. Such procedure was followed and the appellant was granted license, duly approved by the Approving Authority. The license was in force from April 1, 2021 to March 31, 2026. Before the expiry of the said license, an application was filed in terms of Rule 122F, under Form 27E, and subsequently, the

Licensing Authority renewed the license and sent it to the Approving Authority for approval. As the second proviso to sub-Rule 1 of Rule 122F permitted the appellant to continue the business during pendency of the application awaiting approval, the question of disqualifying the appellant did not arise.

4. The notice inviting tender provided that the participant should have a valid license for manufacturing plasma derived products. The bidder was required to produce an attested copy of the license for manufacturing plasma derived products, approved by the Licensing Authority. Mr. Kar submitted that the Licensing Authority and the Central License Approving Authority were separate entities under the law. The tender document did not provide that a license approved by the Central License Approving Authority should only be considered as a valid license. The eligibility criteria only prescribed that the bidder should have a valid license, approved by the Licensing Authority. In this case, the renewed license was issued by the Licensing Authority in the prescribed form. The same was pending approval before the Approving Authority for a substantial span of time. On account of the delay on the part of the Approving Authority before whom the report and the application had been forwarded by the Licensing Authority sometime in June 2026, the appellant could not be put out of business.
5. It was next contended that Rule 122H, specifically provided that an original license under Form 28E or a renewed license under Form 26(I), unless sooner suspended or cancelled, should be valid for a period of 5 years on and from the date on which it was granted or renewed. In this

case, the license was valid for a period of 5 years from the date it was renewed, that is, June 22, 2026. An endorsement of approval by the Approving Authority was a mere formality unless the Approving Authority was dissatisfied with the compliances and decided to either suspend, revoke or cancel the said license. Therefore, the stamp of approval never mentioned the date. The license stood valid from the date the Licensing Authority issued the same and not from the date when the approval was given. If such was the position of law, in that event the objection that the appellants did not have a valid license until approval was granted by the Approving Authority, was not sustainable.

6. Referring to Rule 68A of the said Rules, Mr. Kar submitted that the said rule applied in case of grant of license and not renewal. The Rule 68A originally applied in respect of renewal of license as well, but by an amendment of 2017, the applicability of the said rule also in case of renewal of license, had been omitted. Mr. Kar prayed that the appellant should be allowed to participate in the financial bidding.
7. Learned Advocate General, State of West Bengal, submitted that the appellant did not fulfil the eligibility criteria. The appellant was required to have a valid license. The Licensing Authority had forwarded the renewed license to the Approving Authority for approval. Unless such approval was received, the license did not become valid. The Approving Authority did not act as a mere post office. It had the authority to either suspend, cancel or revoke such license.
8. Under such circumstances, the contentions of the appellant that the approval was a mere formality, could not be accepted. The renewed

license did not become valid until and unless the stamp of approval was affixed by the Approving Authority. The communication dated June 22, 2026 would not have been issued by the Deputy Director 1 cum Licensing Authority, to the Drug Controller(I), for necessary approval, unless the said approval was a legal requirement. Reference was made to Rule 68A sub-Rule 4 of the said Rules in support of the contention that the Approving Authority, if satisfied that the applicant was in a position to fulfil the requirements of the rules, could either grant or renew a license. Thus, even in case of renewal of license, the role of the Approving Authority was vital and the same was a mandatory provision under the law. The second proviso to Rule 122F(1) only permitted the business to continue, but that said proviso did not make an expired license valid, until approval was granted.

9. Reference was made to Rule 81 of the said rules, in support of the contention that, the Licensing Authority and the Approving Authority had a vital role to play in the procedure to be followed for issuance of a license or for approval, thereof. The learned Advocate General further submitted that, it would be an absurd proposition that although the legislature contemplated approval by the Approving Authority, such approval was not a mandatory requirement under the law and a renewed license could be treated as a valid one without such approval. It was submitted that the other bidders had a valid license with the approval from the Approving Authority.
10. Having considered the rival contentions of the parties, we deem it necessary to refer to the following provisions under the Rules of 1945.

11. Rule 2 (b) of the said Rules defines Central License Approving Authority as follows:-

“2[b] “Central Licence Approving Authority” means the Drugs Controller, India or the Joint Drugs Controller India or the Deputy Drugs Controller (India) appointed by the Central Government;]”

12. Rule 21(b) defines Licensing Authority which reads as follows:-

21.(b) “Licensing Authority” means the authority appointed by the Central Government to perform the duties of the Licensing Authority under these Rules and includes any person to whom the powers of a Licensing Authority may be delegated under Rule 22;

13. Rule 22 is quoted below:-

“22. The Licensing Authority may with the approval of the Central Government by an order in writing delegate the power to sign licences and Registration Certificates and such other powers as may be specified in the order to any other person under his control.”

14. The law makes a distinction between the Approving Authority and the ‘Licensing Authority’. Part VII of the said Act deals with manufacture for sale (or distribution) of drugs other than homeopathic medicines. Rule 68A provides for grant of licenses by the Approving Authority. The said provision is quoted below:-

“68A. Grant ³[xxx] of Licences by the Central Licence Approving Authority. —(1) Notwithstanding anything contained in this Part, on and from the commencement of the Drugs and Cosmetics (9th Amendment) Rules, 1992, a licence for the manufacture for sale or distribution of drugs as specified from time to time by the Central Government by notification in the Official Gazette, for the purpose of this rule, shall be granted ⁴[xxx] by the Central Licence Approving Authority (appointed by the Central Government):]

Provided that the application for the grant ⁴[xxx] of such licence shall be made to the Licensing Authority.

(2) On receipt of the application for grant ⁴[xxx] of a licence, the Licensing Authority shall—

(i) verify the statement made in the application form;

(ii) cause the manufacturing the testing establishment to be inspected in accordance with the provisions of Rule 79; and
⁵[xxx]

(3) If the Licensing Authority is satisfied that the applicant is in a position to fulfil the requirements laid down as in these rules, he shall prepare a report to that effect and forward it along with the application ⁶[and the licence (in triplicate) to be granted ⁷[xxx], duly completed] to the Central Licence Approving Authority:

PROVIDED that if the Licensing Authority is of the opinion that the applicant is not in a position to fulfil the requirements laid down in these rules, he may, by order, for reasons to be recorded in writing, refuse to grant ⁸[xxx] the licence, as the case may be.

(4) If on receipt of the application and the report of the Licensing Authority referred to in sub-rule (3) or after taking such measures including inspection of the premises by the Inspector, appointed by the Central Government under section 21 of the Act, with or without an expert in the concerned field if deemed necessary, the Central Licence Approving Authority, is satisfied that the applicant is in a position to fulfil the requirements laid down in these rules, he may grant or renew the licence, as the case may be:

Provided that if the Central Licence Approving Authority is of the opinion that the application is not in a position to fulfil the requirements laid down in these rules, he may, notwithstanding the report to the Licensing Authority, by order, for reasons to be recorded in writing, reject the application for grant¹ [xxx] of licence, as the case may be.”

15. We find that, originally the provision was also applicable in case of ‘renewal’ of licenses. However, from all the places where the expression ‘renewal’ or ‘renew’ had originally existed, they were omitted by the amendment of October 27, 2017, with effect from October 27, 2017. The only exception being the last line of sub-rule 4 of Rule 68A. In our view, upon a harmonious construction of the several provisions of Rule 68A, the omission of the expression ‘renewal’ or ‘renewed’ or ‘renew’ as the case may be, indicated the intention of the Central Government to restrict applicability of Rule 68A to grant of license and not renewal thereof.

16. Part X-B of the said Rules deals with the provisions relating to the requirements for collection, storage, processing and distribution of whole

human blood, human blood components by blood centres, manufacture of blood products and collection, processing, testing, storage, banking and release of umbilical cord blood stem cells. Rule 122F deals with the form of application for renewal of license for operation of blood centre, processing of whole human blood for components/ manufacture of blood products for sale or distribution, collection, processing, testing, storage, banking and release of umbilical cord blood stem cells. The Rule provides that the application shall be made to the Licensing Authority appointed under part VII in Form 27E (in this case) and shall be accompanied by a license fee of Rs. 6000 and an inspection fee of Rs. 1500 for every inspection thereof for the purpose of renewal of license. We find that this is the specific provision for renewal of license. Under the said Rules, the second proviso to Rule 122F(1) is relevant which is quoted below:-

“Provided further that a licensee holding a licence in Form 28C, Form 28E or Form 28F as the case may be, for operation of Blood Centre]/processing of whole human blood for components/manufacture of blood products/collection, processing, testing, storage, banking and release of umbilical cord blood stem cells shall apply for grant of licence under sub-rule (1) before the expiry of the said licence on Form 27-C, Form 27-E or Form 27-F as the case may be, and he shall continue to operate the same till the orders on his application are communicated to him.”

17. The Proviso states that, in the event an application for renewal is pending, the licensee may continue to operate the centre and also the other activities stated in the said proviso, till the orders on his application are passed and communicated to him. Rule 122F(5) provides that if the Licensing Authority is satisfied that the applicant is in a position to fulfil the requirements laid down in the rules, he shall

prepare a report to that effect and forward it with the application to the Approving Authority. In the present case, this exercise has been completed by the Licensing Authority. Rule 122F(5) is quoted below:-

“122F(5) If the Licensing Authority is satisfied that the applicant is in a position to fulfil the requirements laid down in the rules, he shall prepare a report to that effect and forward it along with the application [and the licence (in triplicate) to be granted or renewed, duly completed] to the Central Licence Approving Authority:

PROVIDED that if the Licensing Authority is of the opinion that the applicant is not in a position to fulfil the requirements laid down in these rules, he may, by order, for reasons to be recorded in writing, refuse to grant or renew the licence, as the case may be.”

18. The next stage is provided under Rule 122F(6), which is quoted below:-

“122F(6) If, on receipt of the application and the report of the licensing authority referred to in sub-rule (5) and after taking such measures including inspection of the premises, by the Inspector, appointed by the Central Government under section 21 of the Act, and/or along with the Expert in the field concerned if deemed necessary, the Central Licence Approving Authority, is satisfied that the applicant is in a position to fulfil the requirements laid down in these rules, he may grant or renew the licence, as the case may be:

PROVIDED that if the Central Licence Approving Authority is of the opinion that the applicant is not in a position to fulfil the requirements laid down in these rules he may, notwithstanding the report of the licensing authority, by order, for reasons to be recorded in writing, reject the application for grant or renewal of licence, as the case may be and shall supply the applicant with a copy of the inspection report.”

19. The aforesaid stage had not arrived when the notice inviting tender was issued. The appellant sought to participate on the basis of the renewal granted by the Licensing Authority. The inspection by the Licensing Authority was complete and satisfactory. The Approving Authority has neither initiated any inspection nor had made any query with regard to the ability of the appellant to fulfil the terms and conditions of the rules

and the license. The Approving Authority has kept the matter pending.

In the tender notice, the eligibility criteria provides as follows :-

“Eligibility Criteria:-

- a) Any Firm/Company should have a valid license for manufacturing plasma derived products. The firm should furnish attested photocopy of License for manufacturing plasma derived products approved by the Licensing Authority.
- b) The Firm/Company should furnish the NOC from Drug Controller General, India for collecting excess/surplus available screened of Fresh Frozen Plasma (FFP) from licensed blood bank.
- c) The firm should have a Plasma Fractionation unit in India of their own OR any plasma fractionation unit situated in India can be hired or leased by the firm with submission of authentic documents.
- d) Average turnover of the Firm will be Rs.75 (Seventy Five) Crore for last 3 FYs.
- e) The Firm should have minimum 3(three) years of experience in dealing with plasma fractionation
- f) Dealing with govt. sector may be taken as preference
- g) The company should have the capacity for fractionation of at least 1,50,000 litre/per year
- h) The bidder must be a citizen of India.”

20. We have already discussed that a Licensing Authority has been defined differently from the Approving Authority. Their role is distinct. We find that the renewed license was granted by the Licensing Authority. The contents thereof are quoted below:-

RENEWAL OF DRUG LICENCE IN FORM-28E

FORM 26-I

(See Rule 122-I)

Certificate of renewal of licence to manufacture of Blood Products

1. Certified that Licence no. 02/RR/AP/2013/BP/CC on dated 01/04/2021 in Form 28-E to M/s Ichor Biologics Pvt. Ltd., situated at Survey No. 222P, Turkapally (V), Shameerpet (M), Medchal Malkajgiri District, Telangana – 500078, India is here by renewed with License No. 02/RR/AP/2013/BP/R with effective from 01/04/2026 to 31.03.2031.

2. Name(s) of the items: Products List enclosed with the License.

3. Name(s) of component Technical Staff

(a) Responsible for manufacturing

1. Mr. Manish Aditya G. B. Pharmacy as manufacturing Chemist

(b) Responsible for Testing

2. Mrs. B. Ramya Sri, M.Sc. Biochemistry as Analytical Chemist

Sd/-

Dated: 22.06.2026

GANGI SREEN IVAS”

21. The expression used by the authority was that the license is hereby ‘renewed’ with license No. 02/RR/AP/2013/BP/R with effect from April 1, 2026 to March 31, 2031. In our view, the said appellant fulfils the eligibility criteria. In this connection, Rule 122H is quoted below:-

“122H. Duration of licence.—An original licence in Form 28C or Form 28E [or Form 28F] or a renewed licence in Form 26G or Form 26-I [or Form 26J] unless sooner suspended or cancelled shall be valid for a period of five years on and from the date on which] it is granted or renewed.”

22. It provides that the original license that is issued or renewed under Form 26(I) will remain valid for 5 years on and from the date on which it was granted or renewed. Thus, a harmonious reading of the Rules and the provisions of the Forms would lead us to the conclusion that the license of the appellant does not become invalid because it is pending approval before the Approving Authority and shall be deemed to be a validly issued by virtue of operation of the second proviso of sub-Rule 1 of Rule 122F, till it is either cancelled or revoked or suspended by the authorities.

23. Tender conditions and eligibility criteria are framed by experts. They are supposed to know the provisions of law. When they had used the expression ‘Licensing Authority’ under the eligibility criteria 4(a), in our

opinion, the said expression aligns with the definition of 'Licensing Authority' under Rule 21(b) which has been quoted hereinabove.

24. It is not expected that the tendering authority will not know the difference in the definition of or in roles and the identities of a Licensing Authority and the Central License Approving Authority. A writ court cannot go beyond the terms of the tender. The eligibility criteria of the tender allows participation of any bidder having a license approved by the Licensing Authority, meaning thereby, compliance upto the stage of Rule 122F(5). In this case, the appellant has been disqualified from participating in the bid, although the law permits the appellant to continue with the business for the purpose of which the license had originally been issued and later renewed by the Licensing Authority. Moreover, endorsement by the Approving Authority without any date is indicative of the fact that, pending such approval the license validly issued by the Licensing Authority cannot be treated as invalid. If the contrary argument is to be accepted, then the validity of the license would not be from the date of issuance of the same by the Licensing Authority, but from the date of endorsement by the Approving Authority. The law does not provide so.

25. Under such circumstances, only on account of delay on the part of the Approving Authority in approving the renewed license, the appellant could not be debarred from participating in the financial round. Blood, blood products, plasma derived products have a limited shelf life. That is why the proviso was added to Rule 122 F(1). Continuity in the business is essential so that such rare products which are required to save

human lives, do not go to waste. If the Rules permit the appellant to continue with such business, then there is no reason why the appellant cannot participate in a fresh tender process, which is an integral part of its business activity.

26. Accordingly, the order impugned is set aside. The disqualification of the appellant at the technical round is also set aside. The financial bid of the appellant will be opened along with all other financial bids.
27. The appeal and application are disposed of.
28. Urgent Photostat certified copies of this judgment, if applied for, be supplied to the parties upon fulfilment of requisite formalities.

I Agree

(Arjun Ray Mukherjee, J.)

(Shampa Sarkar, J.)