

**IN THE HON'BLE NATIONAL GREEN TRIBUNAL, SOUTHERN ZONE
BENCH, CHENNAI**

APPEAL NO. 65 of 2024

IN THE MATTER OF: -

Inventprise

.... Applicant

Versus

The Union of India & Anr.

.... Respondents

REPLY AFFIDAVIT TO THE REJOINDER FILED BY THE APPELLANT



Filed by:
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**BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL (SZ)
AT CHENNAI
APPEAL NO. 65 OF 2024**

IN THE MATTER OF:

Inventprise, INC
Redmond, Washington – 98052, USA.

... Appellant

Versus

1. Union of India through Secretary,
Ministry of Environment, Forest and Climate Change,
New Delhi – 110 003.
2. National Biodiversity Authority,
Represented by the Member Secretary,
National Biodiversity Authority,
Chennai – 600 113.

... Respondents

REPLY AFFIDAVIT TO THE REJOINER FILED BY THE APPELLANT

MOST RESPECTFULLY SHOWETH:

I, Dr. B. Balaji, son of G. Badrinarayanan, aged 51 years, Occupation: Government service residing at Chennai, do hereby solemnly affirm and sincerely state as follows:

- I. I am serving as the Member Secretary of the National Biodiversity Authority (NBA), the 2nd Respondent herein, having Office at 5th Floor, TICEL Bio Park, CSIR Road, Taramani, Chennai – 600 113, Tamil Nadu and as such, well acquainted with the facts of the case, borne out of records. I am duly authorized to sign, verify and file this Reply Affidavit to the Rejoinder filed by the Appellant and, as such, competent to defend this case on behalf of the 1st (MoEFCC) and 2nd Respondents (NBA).
- II. This Respondent had perused the Rejoinder filed by the Appellant against the Reply affidavit filed on behalf of the 1st and 2nd Respondents. At the outset, the Respondents deny each and every averment and/or submission made in the Rejoinder, which is contrary to and inconsistent with the averments made and facts stated in the present reply. It is submitted that nothing stated in the Appeal may be deemed to have been admitted by the



B. Balaji

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Respondents unless the same is expressly admitted in the present reply. The Rejoinder filed by the Appellants is a mere repetition of what has already been stated in the Appeal.

1. The Respondent denies the averments in Para B, that the order passed by Respondent No. 2 is arbitrary, illegal and *void ab initio* as Respondent No. 2 does not have any jurisdiction in the present matter. The Hon'ble High Court of Delhi, *vide* its order dated 20.12.2023, directed the 2nd Respondent to give a personal hearing to the Appellant before the Expert Committee of the NBA and decide whether the biological resource falls within the purview of the BD Act. The order stipulated that the decision was to be taken within three months.
2. In compliance with the orders/directions passed by the Hon'ble High Court, the 2nd Respondent constituted an Expert Committee (comprising of Scientists, a virologist from ICMR (NIV) and a representative of the Indian Patent Office) on 17.01.2024 to examine the application filed by the Appellant and also provided an opportunity for a hearing. The NBA constituted an Expert Committee of 26 members and 2 special invitees as subject experts: Dr. Mallika Lavania representing the National Institute of Virology, NIV (ICMR) Pune and Dr. Bhanumathi, Deputy Controller of Patents Designs, Chennai representing, Controller of Patents Designs and Trademark (CGPDTM). Accordingly, the Patent Attorney of the Appellant, Dr. Sudipta Banerjee, attended the hearing in person and submitted the contentions.
3. It is submitted that the 2nd Respondent, based on the recommendations of the Expert Committee, passed an order on 09.03.2024 directing the Appellant to execute the agreement and file Form – I for the already accessed biological resources.
4. The Respondent denies the averments mentioned in Para B that the Patent is already granted and the Patent Office has not raised any such objection, and since the patent stands granted, the Respondent does not have any jurisdiction. It is submitted that as the unwarranted access came to the notice of Respondent No. 2 in the usual monitoring of published patents conducted by Respondent No. 2 to identify such non-compliance cases in and outside India. Based on these monitoring, Respondent No.2 sent an official communication to the Indian Patent Office notifying them of the non-compliance of the provisions under the BD Act and requested them to direct the applicant to obtain the required statutory approvals. Subsequently, the applicant filed the said Form-III application. However, the Indian Patent Office who directed the Appellant to obtain prior approval from NBA, did not wait for the approval instead unilaterally proceeded to grant the patent.



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5. It is submitted that the averments that he was made to run from pillar to post in Para N is denied. It is a legal obligation on the part of the Appellant to obtain necessary approvals from the authorities constituted under the Act if the invention involves biological resources. Respondent No. 2 is the Competent Authority to decide on the grant of prior approvals on the applications filed under Section 6 of the BD Act.

Further, apart from Section 6, the National Biodiversity Authority is mandated to oppose the grant of intellectual property rights outside India under Section 18 of the BD Act.

CHAPTER –IV
FUNCTIONS AND POWERS OF THE NATIONAL BIODIVERSITY
AUTHORITY

18. Functions and powers of National Biodiversity Authority.

(4) The National Biodiversity Authority may, on behalf of the Central Government, take any measures necessary to oppose the grant of intellectual property rights in any country outside India on any biological resource which is found in or brought from India, including those deposited in repositories outside India, or traditional knowledge associated thereto accessed.

Further, a few important provisions in the Patent Act of 1970 deal with pre-grant and post-grant opposition to the patents. Some of the important provisions under the Patent Act are: -

10. Contents of specifications.—

(4) Every complete specification shall—

(ii) if the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely:—

(A) the deposit of the material shall be made not later than the date of filing the patent application in India and a reference thereof shall be made in the specification within the prescribed period;

(B) all the available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit of the material at the institution;



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- (C) access to the material is available in the depository institution only after the date of the application of patent in India or if a priority is claimed after the date of the priority;
- (D) disclose the source and geographical origin of the biological material in the specification, when used in an invention.

CHAPTER V
OPPOSITION PROCEEDINGS TO GRANT OF PATENTS

25. Opposition to the patent.—

(1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground —

(j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

(k) that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere,

(2) At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner on any of the following grounds, namely:—

(j) that the complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used for the invention;

(k) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere, but on no other ground.

6. It is submitted that the above provisions under the Patent Act, provide adequate scope to any persons to oppose the grant of patent and also post-grant of patent. Any applicant using biological resources or the associated traditional knowledge is obligated to disclose the same in the applications. Hence, the claim of the Appellant that Respondent No. 2 does not have jurisdiction in the matter is not justified under the applicable laws. Besides the Biological Diversity Act, 2002 (as amended in 2023), there are adequate provisions in the Patent



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Act, 1970 to oppose any grant of patents (pre and post-grant) if the applicant did not disclose the use of biological resources in the invention.

7. It is submitted that the claim of the Appellant that the invention does not use any biological resource and that the said virus has to be extracted from the host by human intervention and thus, by virtue, it is a value-added product, the same shall not be covered under the BD Act is hereby denied. Any claim on a biological resource that it is a value-added product is to be decided by Respondent No. 2 under the BD Act, and the Appellant cannot assume any such claims without submitting an application to Respondent No. 2.
8. It is submitted that the virus strain 'Rotavirus 116E' fits into the definition of "biological resource" under the BD Act and the details submitted by the Appellant's statement that the rotavirus strain is an isolated strain clearly suggests that the resource under question is living and has a genetic material in it and its components can be isolated.

i. The Appellant is able to multiply the virus in the lab because the strain contains genetic material.

ii. The experts (EC constituted by NBA under Section 13) clarified that a virus contains its own genetic material, which can be either DNA or RNA. This genetic material carries the instructions necessary for the virus to replicate and produce new viral particles. This genetic material carries the genetic instructions necessary for the virus to replicate and produce new viral particles within host cells. The virus uses the host cell machinery to replicate its own genetic material. Studies prove that the rotavirus infects both humans and animals. The said virus strain could not be considered human genetic material as it replicates its own genetic material, thereby producing new viral particles using the human or animal body only as a host.

iii. The Expert Committee (EC) clarified that all major rotavirus vaccines are usually developed using strains of the viruses, and this particular invention follows the exact mechanism (as per the complete specification of the patent application submitted by the Petitioner/applicant). The virus itself or its components serve as an essential biological resource for the production of vaccines to prevent rotavirus infection.

iv. The Appellant accessed a rotavirus strain in its recognizable and separable form, which does not qualify as a value-added product under Section 2(p) of the Biological Diversity Act of 2002.

v. That even part thereof is considered a biological resource as per the definition of Section 2(c) and is in "separable and recognizable form". The EC was of the opinion that even the final vaccine produced by the



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Petitioner/applicant does not qualify as a 'value added product' under Sec 2(p) of the Biological Diversity Act, 2002.

As the rest of the averments in the rejoinder are mere reproductions of what was already stated in the appeal, Respondent No. 2 refrains from repeating the same contentions for the sake of brevity.

In the light of the above, it is most respectfully prayed that this Hon'ble Tribunal may kindly be pleased to dismiss the Rejoinder along with the Appeal and direct the Appellant to comply with the provisions of the Act and pass other directions as this Hon'ble Tribunal deem fit and proper in the case.



DEPONENT

डॉ. ब. बालाजी, भा.व.से. / Dr. B. Balaji, IFS
सदस्य सचिव / Member Secretary
राष्ट्रीय जैव विविधता प्राधिकरण
National Biodiversity Authority
भारत सरकार / Government of India
5वां तल, टायसल बायो पार्क / 5th Floor, TICEL Bio Park,
सीएसआईआर रोड / CSIR Road
तरमणि, चेन्नई - 600 113. / Taramani, Chennai - 600 113.

VERIFICATION

Verified that the statements made above Paras 1 to 8 are true to my knowledge and belief. No part of it is false and nothing material has been concealed therefrom.

Verified at Chennai on the 29th day of April 2025.



Through:

(COUNSEL)



DEPONENT

डॉ. ब. बालाजी, भा.व.से. / Dr. B. Balaji, IFS
सदस्य सचिव / Member Secretary
राष्ट्रीय जैव विविधता प्राधिकरण
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सीएसआईआर रोड / CSIR Road
तरमणि, चेन्नई - 600 113. / Taramani, Chennai - 600 113.

Before me / Attested by
K. ce

के. सिद्धरसु / K. Chitrarasu
सलाहकार (विधि) / Advisor(Law)
राष्ट्रीय जैव विविधता प्राधिकरण
National Biodiversity Authority
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