



National Biodiversity Authority

(An Autonomous and Statutory Body under the Ministry of Environment, Forest and Climate Change, Government of India)

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To

European Patent Office,
Bob-van-Benthem-Platz 1
(formerly Erhardtstrasse 27)
80469 Munich
Germany.

Sir,

Sub: Observation filed under Article 115 of European Patent Convention regarding the use of Indian Biological Resource and non-compliance with India's Biological Diversity Act, 2002.

Ref: European Patent No: EP 1962578 B1 granted by EPO on 4th May 2011

This is with reference to the European Patent No: EP 1962578 B1 granted by EPO on 4th May 2011. This patent titled 'Closterovirus-resistant Melon Plants' was granted to M/s Monsanto Invest N.V. It claims a CYSDV- resistant plant of the species *Cucumis melo* and its parts whether inbred or hybrid.

The invention comprises a genetic element derived from *Cucumis Melo* accession PI313970 having Closterovirus-resistance. This *Cucumis Melo* is an Indian Melon variety which was included into the Russian VIR Database in 1961 and subsequently was transferred to the U.S Department of Agriculture (USDA) in 1966 by the Russian research institute, N.I Vavilov Research Institute of Plant Industry. This melon variety, occurring in India was given the Accession Number PI313970 by the Germplasm Resources Information Network ("GRIN") which is a database maintained by National Plant Germplasm System of the United States Department of Agriculture.

The Convention on Biological Diversity (CBD) to which India and European Union are Parties, affirms the sovereign rights of State over its biological resources. Article 15 specifically upholds the sovereign rights of States to determine access to its genetic resources and insists that access to genetic resources shall be subject to the prior informed consent of Contracting Party providing such resources. European Union being signatory to the 'Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising from their Utilization', had enacted Regulation (EU) No 511/2014 on 'Compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization' in the Union.

Introductory Para 21 of the EU regulation mandates that all users of genetic resources and associated TK should exercise due diligence to ascertain whether genetic resources and associated TK have been accessed in accordance with applicable legal or regulatory

requirements and to ensure that, where relevant, benefits are fairly and equitably shared. Para 29 mandates Member States to check whether the users comply with their obligations, have obtained prior informed consent and have established mutually agreed terms. Para 30 mandates Member States to ensure that infringements of the rules implementing the Nagoya Protocol are sanctioned by means of effective, proportionate and dissuasive penalties. Para 31 urges competent authorities of the Member States to cooperate with each other, with the Commission, and with the competent national authorities of third countries in order to ensure that users comply with this Regulation and support an effective application of the rules implementing the Nagoya Protocol.

Article 4 of the said EU regulation asserts the obligation of users to exercise due diligence and comply with applicable ABS legislations and regulatory requirements. Article 9 obligates competent authorities in EU to detect noncompliance and carry out checks to verify compliance with applicable ABS legislations and regulatory requirements of provider country. This includes the requirement to verify evidence of compliance with national ABS legislations of the providing country including IRCCs or grant of approval from competent national authorities.

The Government of India enacted 'The Biological Diversity Act' in 2002 to regulate access to genetic resources occurring in the country. Section 6 of the Act requires that no person shall apply for any intellectual property right, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of National Biodiversity Authority.

As the source of biological material used in the invention mentioned in European Patent No: EP 1962578 B1, is India, compliance with India's 'Biological Diversity Act, 2002' and its relevant provisions is mandatory. But M/s Monsanto Invest N.V obtained this patent on 'Closterovirus-resistant Melon Plants' without prior approval of National Biodiversity Authority. Under Art. 15(3) of Nagoya Protocol, parties shall as far as possible and as appropriate cooperate in cases of alleged violation of domestic ABS legislation and regulatory requirements. Hence, in compliance with International legal obligations and European Union's Regulation (EU) No 511/2014, it is requested that, the patent be revoked.

Yours faithfully,

(T.Rabikumar)

Secretary, NBA

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SECRETARY

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Enclosures:

1. Excerpt of Sections 3 & 6, Biological Diversity Act, 2002. (India)

THE BIOLOGICAL DIVERSITY ACT, 2002

CHAPTER -II Regulation of Access to Biological Diversity

Section 3.

(1) No person referred to in sub-section (2) shall, without previous approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization.

(2) The persons who shall be required to take the approval of the National Biodiversity Authority under sub-section (1) are the following, namely: -

- (a) a person who is not a citizen of India;
- (b) a citizen of India, who is a non-resident as defined in clause (30) of section 2 of the Income-tax Act, 1961;
- (c) a body corporate, association or organization-
 - (i) not incorporated or registered in India; or
 - (ii) Incorporated or registered in India under any law for the time being in force which has any non-Indian participation in its share capital or management.

Section 6.

(1) No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application.

Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the seating of patent by the patent authority concerned:

Provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof.

(2) The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.

(3) The provisions of this section shall not apply to any person making an application for any right under any law relating to protection of plant varieties enacted by Parliament.

(4) Where any right is granted under law referred to in sub-section (3), the concerned authority granting such right shall endorse a copy of such document granting the right to the National Biodiversity Authority.