ICRISAT
Public Disclosure

ICRISAT has adopted the CGIAR IA Principles[1] which require that CGIAR Centers carefully consider whether to register/apply for (or allow third parties to register/apply for) patents and/or PVP over the CGIAR Centers' respective Intellectual Assets. Under the policy, as a general rule, such applications will not be made unless they are necessary for the further improvement of the Intellectual Assets or to enhance the scale or scope of impact on target beneficiaries, in furtherance of the CGIAR Vision. This disclosure is in fulfilment of the CGIAR IA Principles to provide justifications for the patent applications filed by ICRISAT.

Title of Patent application	**Cytoplasmic male sterile gene *orf147* of pigeonpea, and uses thereof**
Type of filing	PCT Application No. PCT/IN2017/050564 Dt. December 01, 2017
Date of provisional filing	Filed on December 02, 2016 (Application No: 201641041375) in India
Name of applicant	International Crops Research Institute for the Semi-Arid Tropics (ICRISAT)
Name(s) of inventor(s)	1. MATHUR, Pooja Bhatnagar 2. SHARMA, Kiran Kumar 3. GUPTA, Ranadheer Kumar
Territories of protection	India, USA, EPO, Australia and Canada.
Update	Received International Search Report on 9 April 2018. As part of the National Phase entry into the PCT countries scheduled in June, 2019, we have initiated filing national phase application in above mentioned countries during June 2019. Details regarding the PCT application are available on WIPO's Patentscope database and can be retrieved by the link provided below: https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018100590&tab=PCTBIBLIO&maxRec=1000

Background

Pigeonpea [*Cajanus cajan* (L.) Millsp.] is an important high protein (20–22%) food legume grown in the rainfed tropics and sub-tropics of Asia, Africa and South America, cultivated by smallholder farmers. While the self-pollinating nature of legumes is a major bottleneck in exploiting hybrid vigor in these crops, pigeonpea has a unique advantage of being partially out-crossed (20 to 50%). Exploiting this, pigeonpea hybrid technology with A4 (*Cajanus cajanifolius*) cytoplasm involving a three-parent system is considered one of the breakthrough technological interventions in pulse breeding. This male sterile source designated as ICPA 2039 has been transferred into a number of genetic backgrounds and is highly stable across environments. However, the source of male sterility remained unknown for almost a decade, thereby posing a limitation in development of newer and better hybrid

[1] https://www.cgiar.org/wp/wp-content/uploads/ 2018/03/CGIAR-IA-Principles.pdf

pigeonpea varieties for enhanced yield and quality. In a study published in early 2018, researchers at ICRISAT identified the mitochondrial locus responsible for *cms* in line ICPA 2039 of pigeonpea (*Cajanus cajan*), obtained from ICP 2039, a pigeonpea variety from ICRISAT's Genebank.

The identification of a novel mitochondrial orf from the male sterile source provided the basis for an inventive method that involves mitochondrial organeller targeting of synthetic *orf147* and its expression in an anther-specific manner resulting in aberrant anther dehiscence that could lead to male sterility in plants. The gene construct developed was functionally validated in model species and demonstrated its usefulness in developing male sterile lines of crop plants without the need to cross with a source carrying *cms* cytoplasm. The introduction and expression of this gene construct in a female parent provides opportunities to develop hybrid seeds in a range of crops. Constructing a male sterile system using this gene construct would overcome the bottlenecks associated with the instability of CMS under certain conditions, parental and hybrid seed purity issues and negative impacts of aberrant mitochondrial genes on the performance of hybrids,. Moreover, this approach will save time and potentially can generate large number of such parental lines in crops where hybrid technology does not exist.

The protection has been sought for this platform technology where a method of obtaining a cytoplasmic male sterile plant harboring in its genome, a DNA segment that is synthetic in nature is assembled in a specific manner to achieve the male sterility in crops. Since those skilled in the art for convenience and commercial benefits are capable of creating variations and make exclusive use of this knowledge to their advantage, it was decided to protect this technology for the benefits of smallholder agriculture communities. Besides, ICRISAT's control of this technology will ensure that no single private sector company gains exclusive control of this trait. Moreover, for future work on the completeness of this technology, a patent will support and incentivize investment for its further development.

Origin of genetic material from which the innovation is derived

The mitochondrial locus responsible for *cms* was identified in the pigeonpea line ICPA 2039 which was originally obtained from a cross between ICPW 29, an accession of *C. cajanifolius* and ICP 11501 from ICRISAT's Gene bank listed in the Annex-I. of the ITPGRFA. The variety/biological material per se is not being protected.

The invention deals with a dominant negative gene, a polynucleotide fragment which encodes a polypeptide, expression of which in mitochondria in an anther-specific manner results in cytoplasmic male sterility. The protected technology is a process patent where a method of obtaining a male sterile plant harboring in its genome a DNA construct, that is synthetic in nature and is assembled in a specific manner to achieve the desired outcome (in this case, male sterility which is a universal component of hybrid systems across crops). The invention in no way relied on the use of traditional knowledge of indigenous communities.

Rationale for this patent

ICRISAT works on developing international public goods (IPGs) that are accessible to public sector researchers for enhancing agricultural research in the National Agricultural Research Systems (NARS). This is done mainly through publications and capacity building activities.

However, there could be instances where the private sector could access such IPGs and use them for their commercial gains. While this can be instrumental in outreach of new products and technologies to the farmers, it can also result in higher cost of such technologies due to charging of high "technology fees" by the private sector companies that may not be affordable by the smallholder farmers. Moreover, gains made by the private sector do not return to the public, especially the smallholder farmers.

Importance for the further improvement of technology

- Recognizing the importance and application of this platform technology, i.e. "*orf147*" gene, there is likelihood that private sector companies may exploit its openness by either refined patenting based on this invention, or secure blocking patents that would limit its ability to improve crops including the CGIAR mandate crops.

To enhance the scale or scope of impact on target beneficiaries

- Proposal for patenting is intended to prevent private companies from claiming IPRs over this important invention and to ensure that this technology will remain available to scientists working for sustainable agriculture in developing nations.
- IP protection for this innovation is a defensive strategy to ensure its availability as a public good, besides ensured freedom-to-operate for ICRISAT and its partners.
- The utility of this invention for hybrid seed production in pigeonpea, if not protected could result in knowledge/technology being readily available to the private sector that could, in turn protect it as such or with some tweaking, thereby imposing restrictions to its public use, including ICRISAT. ICRISAT can leverage its position by providing this technology to specific private sector companies in a non-exclusive manner, where a better price control mechanism for seeds can be negotiated. This would also provide possibilities for generating additional funds for future R&D efforts on advancing the hybrid seed technologies for our other mandate crops. Besides, this also provides opportunities for favourable negotiations with private sector partners to access their propriety technology/s for use in developing public good/s.
- Considering that this platform technology/gene has potential for inducing male sterility in other crops, this makes it a desirable trait for exploiting heterosis in crops which do not have hybrid system.

Value and/or income it will generate

The key to successful commercial production of hybrid seeds is sufficient control of male sterility. While it will be difficult to put a dollar value for this technology at this time, so far, we have approached Ag-biotech and seed companies who shop for new technologies. Following discussions with the interested parties and our own efforts on proper evaluation of the technology for specific applications, a better valuation of the potential gains will be arrived at on a case-by-case basis. In scenarios where fees and/or royalty provisions will apply (on a case-to-case basis), the negotiated licenses will include provision of an obligation to contribute to the Benefit Sharing Fund of the Multi-Lateral System of the ITPGRFA.

Dissemination strategy

ICRISAT will implement a responsible dissemination strategy with all partners in the countries where the technology will be used for further development and deployment with due consideration to the appropriate legal and hybrid seed production systems in the target

crops and geographies to ensure further technological improvements with a commitment that the smallholder farmers benefit from this technology. The NARS partners and public research organizations will be provided access to royalty-free non-exclusive licenses for use in their individual or joint R&D and plant breeding, with a commitment for impact. ICRISAT with its technology partners (both public and industry) is committed to providing seed varieties tailored to the needs of smallholder farmers, and a technology such as the one being protected will aid hybrid breeding, ensure quality seed distribution and adoption for local suitability across regions. Empowering the smallholder farmers with hybrid technologies will support these communities helping them overcome the challenges agriculture faces in the harshest of conditions.

In furtherance of the CGIAR Vision:
This proposal for patenting is to ensure broad distribution of this technology through a flexible licensing policy. The rationale behind this proposal is to make this technology available to ICRISAT, other CG Centers, NARS and other public research organizations in order to continue CGIAR mission of disseminating science for sustainable agriculture.

Public disclosures
The subject matter of the invention has been published in the "Plant Molecular Biology" journal and can be accessed at: https://link.springer.com/article/10.1007/s11103-018-0728-7.

Pathway of the innovation to market and to smallholder farmers
The dissemination strategy for this platform technology for the benefit of public research institutions and NARS has been indicated above.

Strategy, business plan for each commercial partner/company
- Strategy involves both co-development and technology transfer on case-by-case basis.
- Its full exploitation in pigeonpea requires a tight loop CMS-Rf system to have a better technological control. Preliminary discussions are ongoing with some Indian seed companies targeted for pigeonpea.
- To utilize male sterility induction by gain of function, there has been a lot of interest from several industry partners and international institutions (Australia, Canada).
- Discussions are ongoing with the Department of Biotechnology-Biotechnology Industry Research Assistance Council (BIRAC) of the Government of India, and Technology Transfer Experts in India.
- This platform technology is being negotiated to develop a collaborative research agreement for developing scalable hybrid systems in crops. With the support from industry partners, ICRISAT will work on continuous exploration of molecular regulatory networks controlling male fertility so as to greatly facilitate hybrid vigor utilization in breeding and field production in a range of crops.
- The feedback obtained so far point towards the need for demonstrating the utility of the gain-of function gene in crop species. While we do have data on model plant species (Arabidopsis and tobacco), a proof-of-concept on any crop will further strengthen our business plans with the technology. This work is currently ongoing with a few of ICRISAT mandate crops.

Compliance to national laws

All our existing and proposed activities would strictly be in-line with the Indian Biological Diversity Act. We are also seeking approval from the National Biodiversity Authority of India (NBA) by submitting the appropriate Form, as the Act states that any person who intends to obtain IPRs for any invention based on any biological resource obtained from India has to seek prior approval. Unless and until this approval is submitted to the Indian Patent Office, they will not even consider the patent application for examination for an Indian Patent. In addition, the NBA approval and Patent Grant would trigger the specific ABS compliance issues. ICRISAT adheres to these requirements completely.

Through its patent rights, ICRISAT will control this technology and will ensure that no single private sector company gains exclusive control of this platform technology. The knowhow and the gene(s) constructs shall be made available to NARS and other public research organizations for use in a range of crops under appropriate Material Transfer Agreements in a non-exclusive manner for the benefit of smallholder farmers. ICRISAT will not exercise its patent rights in ways that limit access to the original in-trust germplasm. ICRISAT will always allow the technology to be used at no cost by public researchers in countries/jurisdictions where the technology is protected (India, USA, Canada, Australia, and Europe) and make the technology available for emergency uses. Under specific collaborations with partners/ NARS, ICRISAT will work with due biosafety compliance as per the host country regulations.