

## **The Plant Variety Authority and Bt cotton: A case of regulatory capture?**

In India, the creation of a new plant variety by any breeder, whether a seed or a biotech research company or an individual farmer, is protected under the Protection of Plant Variety and Farmers Right Act, 2001 (“**the PPVFR Act**”). The PPVFR Act is administered by the PPVFR Authority (“**Authority**”).

A transgenic plant variety is a plant variety that has one or more genes from a foreign organism, such as bacteria, incorporated in it by a biotechnology process in a lab. These genes confer certain additional ‘traits’ to the plant variety. Once a transgenic plant variety is developed and approved for release in to the environment, other transgenic plant varieties can be created from it by transferring the relevant genes to other plants by natural biological processes, such as selecting and crossing of plants.

Ordinarily, a transgenic plant variety ought to be registrable under the PPVFR Act so long as it satisfies the NDUS criteria (Novelty, Distinctiveness, Uniformity and Stability). To register a transgenic variety, additionally, the Authority requires an applicant to submit a No Objection Certificate (“**NOC**”) obtained from the entity that first introduced the gene into the plant. In the case of Bt cotton, that entity is Monsanto, and every Indian breeder who has since wanted to protect a new Bt plant variety has had to obtain an NOC from Monsanto as part of its application for registration. As it turns out, Monsanto has rarely offered an NOC unconditionally. As a result, Indian breeders who want to register a new Bt plant variety must enter into an agreement with Monsanto in exchange for the NOC, an agreement that the Indian seed companies find exploitative<sup>1</sup>. This article attempts to understand how the requirement of an NOC came about, and whether it has any legal basis at all or not.

### **The legal position**

On 1 September 2015, the Authority issued a public notice that the general guidelines for registration of essentially derived varieties was approved in its 23<sup>rd</sup> Meeting held the previous month. These guidelines introduced the NOC requirement under section

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<sup>1</sup> Pleadings in W.P No 30734/2016 filed by M/s Seedsmen Association before the HC of Hyderabad.

23 of the PPVFR Act read with Rule 35. Strangely enough though, the Authority had been demanding such NOCs since at least 2009<sup>2</sup>, at least six years before the Authority purportedly approved the requirement in its 23<sup>rd</sup> Meeting. Further, Section 23 read with Rule 35 relates to the manner of testing essentially derived varieties, and the connection of such a legal provision with an NOC requirement is tenuous, to say the least.

Elsewhere, in response to an RTI query<sup>3</sup>, the Authority claimed that the NOC requirement was stipulated under Section 18 of the PPVFR Act, and in particular, the requirement of declaration under Section 18, read with Section 20 and Section 23. The substantive requirement is contained in Section 18, which deals with the form of application for registering a variety, as reproduced in relevant part below:

Registration of Plant Varieties and Essentially Derived Variety

**Section 18: Form of Application**

Section 18(1)(h): Every application for registration shall contain a declaration that the genetic material or parental material acquired for breeding, evolving or developing the variety has been lawfully acquired;

Section 18(1)(i): Every application for registration shall be accompanied by such other particulars as may be prescribed.

Section 2(q): "prescribed" means prescribed by rules made under this Act;

At the very outset, Section 18 provides for the form of application, and the information to be submitted, for registering plant varieties. Section 18 is applicable to **every** application for registration. By extension, the requirement of 'declaration' under Section 18(1)(h) would be for all varieties, and not just transgenic varieties. Thus, if the Authority is stipulating a requirement of NOC, it should be for all varieties and not just transgenic varieties alone.

It is also relevant to note that Section 18(1)(h) refers to a declaration to be made by the applicant, and does not require the applicant to obtain any form of "authorization" from a

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<sup>2</sup> Letter to M/s Nuziveedu Seeds from the PPVFRA dated January 7 2009 for registration of Mallika Bt2

<sup>3</sup> Letter dated Dec 8 2016, PPV&FR/30-4/07/RTI/2700 in response to RTI request PPV&FRA/RTI/2016/67 filed by N Naga Babji

third party. Indeed, the PPVFR Act uses the terms ‘authorization’ and ‘declaration’ in various provisions for different purposes. For example, section 30 requires an authorization from the breeder when the breeder’s registered variety is to be used repeatedly for commercial purposes. The word “declaration”, as commonly understood, means “making an official statement about something”, and cannot arguably be stretched to mean obtaining permission or an NOC from the creator of a trait.

Section 18(1)(i) requires that additional information as may be ‘prescribed’ may also be required to be submitted in the application for registration. But whatever is “prescribed” must necessarily be prescribed under the rules made under the PPVFR Act (Section 2(q)). Therefore, if an NOC from the trait provider is contemplated under the PPVFR Act, it ought to have been prescribed either under the PPVFR Act or the PPVFR Rules 2003 (“**PPVFR Rules**”); but no reference to an NOC is contained in any of these legislations.

Section 95(1) of the PPVFR Act permits the Authority to issue regulations for registration of plant varieties. However, any such regulations can be issued only after prior approval of the Central Government and after notification in the official gazette. The Authority notified the Protection of Plant Varieties and Farmers’ Rights Regulations, 2006 (“**PPVFR Regulations**”) in December 2006. These regulations provide for two application forms (Form I and Form II) to be filed when seeking registration, either of which may be used to apply for registration as relevant. Both forms are extremely detailed, and have an exhaustive list of documents that must be submitted along with the form. Neither the forms nor the accompanying list of attachments mention any requirement of obtaining or submitting an NOC. Interestingly, the forms already include the various stipulated declarations, such as the declaration under Section 18 (1)(h) of the PPVFR Act.

Arguably, the Authority cannot impose additional conditions for registration, such as the requirement of an NOC, under the PPVFR Act of its own accord. Such additional conditions can only be imposed by the Central Government through an amendment to the PPVFR Act. The Authority has, therefore, in imposing this additional requirement of obtaining a NOC, overstepped its authority.

The NOC requirement was also recently challenged before the High Court of Hyderabad by some seed companies. The High Court directed the Authority to hear the matter on

merits and pass an order in accordance with law. The matter was finally heard by the Registrar General of the Authority, and not the Authority itself, only for the Registrar General to state that since the NOC requirement was introduced by the Authority, the Authority must hear the matter again. What is interesting is that the order of the Registrar General admits that the reason for requiring an NOC was to safeguard the patent rights of Monsanto! It says that the order deals “with the issue to dispense with the requirement of submission of NOC from patent holders of patented genetic material by the applicants for registration of plant varieties who have used the patented genetic material in the development of their varieties applied for registration.”

However, the statutory powers of the Authority do not include protecting patent rights, if any, of a party, which are already protected under another specific law. The Authority should restrict its role to the protection of breeders’ rights for varieties registered under the PPVFR Act. Any question of patent infringement of patents should be decided by other designated and competent authorities, as per law. The Patents Act, 1970 (“**Patents Act**”) does not enable the Authority to enforce or determine validity of patents, and indeed, the Patents Act categorically excludes plants and seeds and varieties from patent protection. By taking on this policing role, the Authority is venturing, unlawfully, into territory outside its competence and jurisdiction.

The NOC requirement also has a number of harmful consequences: Firstly, Section 8 of the PPVFR Act casts a duty on the Authority to promote development of new varieties and to protect the rights of the farmers and the breeders. An NOC requirement arguably discourages breeders from creating new transgenic varieties and suppresses farmers’ and breeders’ rights, instead of protecting them. This especially applies with respect to breeders’ rights under Section 30 of the PPVFR Act to use any variety as an initial source of variety for creating another new variety. The NOC stipulation has led to a situation where the public-sector cotton-breeding programme, has more or less been completely disbanded as breeders are unable to breed new varieties and have had to stop cotton varietal or hybrid breeding with Bt traits. Hundreds of small and medium seed companies have also gone out of the cottonseed business due to the present circumstances.

Secondly, the NOC requirement has serious consequences for the benefit sharing provisions under the PPVFR Act. Under Section 26 read with Rule 43 of the PPVFR Act, any

person or group of persons or firm or governmental or non-governmental organization can submit its claim for benefit sharing on the commercialization of a hybrid or variety developed using a plant variety containing the originally developed Bt trait. The benefit sharing amount must be determined by the Authority, and must be fair and reasonable. It must also address the interests of all the parties i.e., breeders, the Bt trait provider and farmers. Further, the amount must not be high or arbitrarily fixed. In the Bt cotton case, the procedure Monsanto ought to have followed was to have sought benefit sharing rights for its Bt cotton variety by applying to the Authority. In turn, the Authority would determine the amount that Monsanto could claim from the Indian seed companies. This was clearly not something Monsanto was agreeable to. Instead, it chose to decide its fees independent of any governmental interference through the NOC. The requirement of an NOC shifts the power to determine benefit sharing into private hands. As shown by the Bt cotton episode, the trait provider has a tendency to misuse the NOC requirement to make seed companies enter into exploitative agreements and charge exorbitant trait value from seed companies in exchange for an NOC.

An NOC also causes loss of revenue to the Authority. Under section 35 of the PPVFR Act, the Authority may impose a fee to be paid annually by every breeder of a variety, agent and licensee registered under the PPVFR Act. The fee is determined on the basis of benefit or royalty gained by such breeder, agent or licensee in respect of the variety, for the retention of their registration under the PPVFR Act. In the Bt cotton case, the trait provider has conveniently bypassed the Authority, but is placed in a powerful position where it is able to extract rents from prospective breeders.

The requirement of an NOC also causes loss of revenue to the National Gene Fund (“NGF”) constituted under Section 45(1) of the PPVFR Act. The fund is utilized for any amount to be paid by way of benefit sharing, the compensation payable to the farmer/community of farmers, the expenditure for supporting the conservation and sustainable use of genetic resources including in-situ and ex-situ collections and for strengthening the capability of the panchayat in carrying out such conservation and sustainable use. A key contributor to the NGF is the benefit sharing amount received from the breeder of a variety. The NOC requirement enables a trait provider to by-pass the NGF causing significant loss of revenue to it, and obstructs the fulfilment of the NGF’s objectives.

Lastly, the requirement of an NOC reduces the dignity of the Authority by making it an agency of a private party. The ceding of its statutory powers by the Authority has facilitated a private party to unilaterally fix trait value, something that is likely to have a harmful effect on Indian agriculture in the future.