

**COMMENTS/SUGGESTIONS IN RELATION TO THE LICENSING GUIDELINES AND FORMAT FOR GM
TECHNOLOGY AGREEMENT**

Section A

1. **MATTER SUB-JUDICE:** The Licensing guidelines and formats of a license agreement in relation to GM technology and GM trait as defined by Sections 2(g) and 2(h) of the Cotton Seed Price (Control) Order, 2015 (*hereinafter referred to as "CSPCO"*) is premature and appears to be issued in haste at least for the following reasons:
 - a. The draft licensing guidelines and format for GM technology Agreement has been issued under CSPCO, which is **"currently under challenge"** before the High Court of Delhi;
 - b. The notification of 9th March 2016 fixing the maximum sale price (MSP), trait value of Bt cotton seeds makes a specific reference to Monsanto-Mahyco licensing their patented BT cotton technology to 50 companies. This notification has also been challenged by Monsanto-Mahyco and is **"currently pending"** before the Delhi High Court.
 - c. Further, the said notification of 9th March 2016 refers to a CCI complaint filed by Department of Agriculture, Co-operative and farmers welfare along with the Indian seed companies namely, M/s Nuziveedu Seeds Limited (NSL), M/s. Prabhat Agri Biotech Limited (PABL), Pravardhan Seeds Private Limited (PSPL) against Monsanto- Mahyco. By the order dated 10th February 2016, the CCI has ordered an investigation under Section 26(1) of the Competition Act.

Therefore as the CSPCO and the notifications issued thereunder are SUB-JUDICE, the Government ought not to have interfered by further issuing the licensing guidelines.

2. **PREAMBLE/ OBJECTIVE OF THE LICENSING GUIDELINES INCONSISTENT WITH THE CSPCO:**
 - a. The preamble of the CSPCO [. G.S.R. 936(E)] of 7th December 2015 states the following:

*"An Order has been issued for providing an effective system for fixation of sale price for cotton seeds to ensure their availability for the **farmers** at **fair, reasonable and affordable prices.***

*"That there is **demand from the farmer** to regulate price of genetically modified cotton seeds such as seeds of BT cotton which has found to be highly priced."*

- b. Clearly the objective of the CSPCO of 7th December 2015 issued by the Ministry of Agriculture and Farmers welfare is to ensure **availability to farmers** of cotton seeds at a fair, reasonable and affordable price and not to **private seed companies** who are also working for a commercial gain. The focus of the licensing guidelines is to provide an automatic compulsory license to all seed companies and NOT TO FARMERS that approach the licensor.
- c. If at all the licensing guidelines have to be formulated, they ought to be between the licensee who is the holder of GM technology/ GM trait and the farmer (licensor). If the Government is serious in ensuring availability to the farmers, mechanism should be created such that the procurement of the seeds by the farmers is made easy.

3. LICENSING GUIDELINES IN CONFLICT WITH THE IP LEGISLATIONS: The CSPCO guidelines as well as licensing guidelines issued thereunder are in complete violation of the several legislations including IP legislations:

a. INDIAN PATENTS ACT:

- i. Under the Indian patents act, GM technology is patentable.
- ii. Novel gene sequences that may be directly or indirectly responsible for expression of a GM trait are patented under the Indian Patents Act.
- iii. The India Patents Act, provides exclusivity to a patentee a term of 20 years and any violation of the same amounts to infringement under Section 48 of the Indian Patents Act.
- iv. The Indian Patents Act provides sufficient safeguards in the form of compulsory license on any one or more grounds namely,

- that the reasonable requirements of the public with respect to the patented invention have not been satisfied or
 - the patented invention is not available to the public at a reasonably affordable price or
 - that the patented invention is not worked in the territory of India.
- v. The Government to right to use the patent upon payment of adequate compensation to the patentee under the provisions of the Indian Patents Act
- vi. Further the Indian Patents Act does not contemplate any procedure for “**automatic licensing of patent rights**” between private parties

**b. THE PROTECTION OF PLANT VARIETIES AND FARMERS RIGHTS ACT, 2001
(HEREINAFTER REFERRED TO AS PVP ACT)**

- i. The PVP Act clearly recognizes providing **monopoly** to a farmer or a breeder and to encourage development of new varieties of a plant in order to accelerate the agricultural development in the country and stimulate investment for research and development for both in public and private sector for development of new plant varieties.
- ii. The said act was a creation of the Parliament in order for India to honor their international obligations under Article 27(3) of the TRIPS Agreement relating to protection of plant variety.
- iii. The PVP Act clearly covers protection for transgenic variety (which inherently incorporates GM trait) and grants the proprietor exclusivity /monopoly for a limited period;
- iv. The government while promulgating the PVP Act had taken into account the farmers and breeders interest and introduced provisions relating to compulsory license to any person interested on any of the following grounds under Section 47:

- *That the reasonable requirements of the public for seed or other propagating material of the variety have not been satisfied or*
- *that the seed or other propagating material of the variety is not available to the public at a reasonable price.*

Therefore, there are at least two legislations that create monopoly for patented GM technology as well as new plant varieties. A right created by the statute cannot be diluted or taken away by administrative orders of the Government. Further, all government intervention should be consistent with the law of the land and should not contradict or take away a substantive right given by any legislation for the time being in force in the country.

4. TRIPS VIOLATION

- CSPCO order as well as the licensing guidelines is in clear violation of Articles 27(3), 28 and 31 of the TRIPS obligation at least for the following reasons:
 - Article 28 (1) confers on the patentee to prevent unauthorized use of the patented technology;
 - Article 28(2) permits the patentee to deal with a license on their own volition;
 - Article 31 permits member states to provide provisions of compulsory license, the terms and conditions of which have to be determined on a case to case basis;
 - Voluntary negotiations is a pre-condition for the grant of a CL

The Licensing guidelines are in complete disregard to the TRIPS provisions and appear to be one size fit all guidelines, irrespective of the nature of technology and investment made in relation to proprietary technology

5. VIOLATIVE OF ARTICLE 14 AND 19(G) OF THE CONSTITUTION OF INDIA

The said guidelines seem to be discriminatory under Article 14 of the constitution and Article 19(1)(g), the right to carry on trade or business.

6. **AGAINST THE NATIONAL IPR POLICY-** The said guidelines are against the national IPR policy that lays emphasis on research and innovation in the field of biotechnology and agro-biotech.
7. **AGAINST THE VISION OF MR. PRIME MINISTER:** The guidelines are further against the vision of the Mr. Prime Minister of India which is to double farmers' income by 2022. If the farmers are denied access to new technology, there is no way that this vision to double farmers income by 2022 is achievable, as new patented technologies are working in direction of high yield protection against pests and to deal with abiotic stresses such as drought, salinity, etc.

SECTION B

COMMENTS ON THE LICENSING GUIDELINES AND FORMATS FOR GM TECHNOLOGY ARRANGEMENTS FOR COMMENTS/SUGGESTIONS

Notwithstanding our comments that the said CSPCO order, and the GM licensing guidelines notification issued thereunder are in contravention and violation of the Indian Patents Act, PVP Act as well as the TRIPS agreement as stated under Section A, our comments to the draft licensing guidelines is as follows:

I. Preamble

- a. The format for the GM technology licensing agreement **cannot** include clauses that are not contained or provided by the CPSCO order. The said notification therefore should not be an attempt to **redefine or modify** the order of 7th December 2015 and 9th March 2016.
- b. **Paras 2 to 4** of the preamble are unnecessary in the light of the fact that the same only recognizes that IP protection is available for several aspects of GM technology under the Indian Patents Act or through the Protection Of Plant Varieties and Farmers Rights Act, 2001. Further, the said paragraphs go beyond the mandate of the CSPCO by outlining as to what is patentable and what is not patentable under the Patents Act as well as in bio-technology

what can be allowed/disallowed under the Protection Of Plant Varieties and Farmers Rights Act, 2001.

- c. **Paragraph 5** is in complete violation and contradicts the preamble of the CSPCO order. While the objectives of CSPCO order is “providing availability to farmers at fair, reasonable and affordable prices”, the guidelines is an attempt to benefit the Indian seeds companies by providing the said seed companies, access to proprietary GM trait / GM technology without any restraint under the FRAND mechanism.
- d. FRAND is an expression alien to biotechnology and has primarily been used for industries such as telecom, DVD players where for any patent to be considered as a standard essential patent it has to be incorporated in the technology or else the technology will not work. In other words, there is **no substitute available.**
- e. The **non-discriminative mechanism** is not a part of the CSPCO order as the preamble only prescribes fair, reasonable and affordable prices whereas the guidelines refer to fair, reasonable and non-discriminative mechanism.
- f. Further, in a FRAND mechanism, the licensor is willing to give a license to the licensee and is not in the nature of being a compulsory/mandatory license where the licensor has no control over the license arrangement including terms and condition regulating the said license agreement such as determining the licensor, territory, duration of the agreement, royalty etc.

The guidelines and complete departure from the intent of the CSPCO order.

II. CLAUSES 3 & 4

- Clause 3(4) makes it mandatory by use of the expression “shall” for the licensor to consider all license applications made to them;
- **It appears that the licensing guidelines have been made to benefit the Indian seed companies who work for commercial gain and wish to**

benefit from the research and investment made by the licensor and is in no way intended to benefit the farmers.

- Clause 3(4) –while this clause talks about the benefit of the **cotton farmers, it** concludes by stating that the GM trait should not become a barrier for entering the market by entering eligible said marketing by an **eligible seed company;**
- It is a challenge for the farmers to possess or have access to a lab as required by Clause 3(3)(ii) to carry out necessary tests for breeding and testing of GM traits.
- Clause 3(5) – this provision is in contravention of all legislations and there cannot be an automatic license procedure for a technology owned by the licensor under the Indian patent regime. This clause has taken away the rights granted to a patentee under Section 48 of the Indian Patents Act as well as under Section 28 of the PVP Act (registration to confer rights).
- Clause 3(5) is in direct contravention with the licensing provisions contained in several IP legislations. There is nothing defined as to what is a FRAND mechanism. In any event, the pricing on fair, reasonable and affordable prices is to be determined by the licensor.
- Under Section 3(i) of the Indian Patents Act, an amendment was effected by the Patents Amendment Act of 2002 wherein the Act clearly provided that any process for the treatment of plants to render them free of diseases or to increase of their economic value will be considered patentable. Therefore, a patent for a process for treatment of a plant such as cotton so as to render them free of disease or become resistant to bollworm is clearly patentable under the Indian Patents Act.
- Section 3(5) cannot being a **deeming provision** wherein a license is granted automatically if the licensor fails to meet the obligation or grant a license to a prospective licensee.

- Clause 3(7) – This provision is ultra vires and violative of a contractual relationship between two private parties that renders all existing GM trait license agreement as being invalid to the extent they contradict the guidelines that the licensor-licensee are forced to enter into a new license agreement within 30 days.
- Section 3 in a way amounts to giving up all IP protection that the licensor might own by issuing automatic/compulsory licenses to a licensee which in a way is equivalent to **forced surrender** of the IP rights.

III. TRAIT VALUE- CLAUSE 4

- Section 4(1) suddenly introduces the **benefit of the farmers** while the focus of Section 3 was only in relation to **benefit to seed companies**.
- The order of 9th March 2016 has not provided any basis for arriving at the calculation of fixing trait value or MSP of GM cotton seeds.
- Having said this, the licensing guidelines should not have dealt with trait value/seed value as the High Court of the country has clearly held that the Central Government cannot issue notifications/order that regulate or fix trait value.
- Clause 4(2): This is an **extremely subjective provision** (fact and evidence based) and cannot form a part of the licensing guidelines. This efficacy of a trait value has to be tested based on the facts and evidence. The fixing of trait value with regard to 'efficacy' of the GM trait, the reward and return of investment already made by the proprietor, the year of obtaining a patent and commercialization of trait in India and the gradual reduction of trait value has to be based on facts and evidence and the Central Government cannot have a **ONE SIZE FITS ALL** rule when fixing the trait value. Further, there is no rational that has been provided with regard to reduction of trait value from the 6th year onwards.
- **Clause 4(3) and 4(4):** This provision is based on a **speculation** that a GM traits are expected to have a limited period of efficacy and the proprietor is not entitled to any trait value after the loss of efficacy based on a subsisting

and valid patent. In other words, this provision is clearly an attempt to reduce the life of a patent term from 20 years to around 6 years

IV. Clause 5- UPFRONT FEES

The maximum ceiling price in relation to the upfront fee payable by the licensee is 25 lakhs is irrational and arbitrary.

SECTION C

COMMENTS ON THE FORMAT FOR THE GM TRAIT (Annexure)

The clause of the Annexure are ultra-vires and violative of the provisions of natural justice and Article 14 of the Constitution.

The format provided by the said notification is an attempt to create subordinate legislation.

- **Clause 1 & 2** should not therefore form a part of the license agreement.
- **Clause 5:** A GM trait transfer according to the format can either be exclusive or non-exclusive. The licensing guidelines cannot take away the exclusivity granted to the proprietor of the GM technology. Further, the license agreement can be confined to a specific territory/jurisdiction within India and need not be granted on the **whole of India basis**.
- **Clause 7:** This clause is contrary to the fundamental licensing principles in particular, in relation to IP. If the licensee incorporates a GM trait and develops a new variety, the IP in the new variety might belong to the licensee but that does not mean that the licensor has no right over the GM trait that is included in the said new variety. In other words, while the licensor can have a patent for the GM trait as well as protection under the PVP Act, the licensee can yet obtain a protection under the PVP Act for the new hybrid but will not be able to commercialize it as it would clearly amount to infringement of the rights of the licensor under the Patents Act. Further, by incorporating a GM trait to generate a new hybrid variety does not take away or dilute the original proprietors IP rights in the said GM trait. Therefore, **commercial exploitation rights** cannot vest in the licensee in the transgenic cotton variety without the said licensee having obtained the authorization of the licensor/the holder of the patent.

- **Clause 8:** Extensive studies and market surveys have been conducted in order to identify and develop a GM trait and the research and the agricultural industries is a heavy investment sector. Once a GM trait is developed it has to go through regulatory approvals for which the applicant generates and submit extensive data. In the absence of adequate data exclusivity or data protection laws in India, providing the information relating to approvals to the licensee/Controller, is like giving the GM technology on a silver platter without the licensee having made any investment in the said development of the GM trait
- **Clause 9:** The expression “proprietary cotton hybrids and parental lines” should be replaced with “legally acquired cotton hybrid”. Irrespective of commercial life of a GM trait, if the GM trait is patented, it is entitled to a term of 20 years. Further, the commercial life of being a GM trait as being 10 years is arbitrary as it varies on a case to case basis.
- **Clause 10:** If any transgenic variety developed by the licensee incorporates the GM trait of the licensor, the licensee should not be entitled to sub-licence either the transgenic variety incorporating the said GM trait or the GM trait itself without an approval from the licensor as the act of sale of the said sub-licensee clearly amount to infringement
- **Clause 11:** The indemnity clause on the licensor is irrational. Any due diligence activity prior to entering into license agreement is always conducted by the licensee.
- **Clause 15:** Prior to the license agreement, no licensee is authorized to incorporate a GM trait into their variety/hybrid for commercialization.

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