APBREBES **Association for Plant Breeding for the Benefit of Society**

Working paper #1

Global, Profitable, Secret? DNA Fingerprints for Enforcement of UPOV's Plant Variety Protection

According to the UPOV Conventions, it is up to member states to provide for appropriate legal remedies for the effective enforcement of the Conventions. But UPOV member states are being expected to play a crucial role in providing expensive technical and administrative infrastructure, as well as legally questionable confidentiality arrangements, in order to enable already powerful seed companies to enforce royalty income on the basis of evidence from DNA fingerprints of suspected seeds or plant material.

Background

DNA fingerprinting as applied to plant breeding is also increasingly being used in some countries to enforce intellectual property rights, including plant variety protection.[1] Some seed and planting material industry associations are pushing international organisations to help pave the way to increase royalty incomes based on DNA fingerprints.
Issues that some industry associations are addressing include, among others:

- Conflicts among breeders: New varieties are often derived from an existing protected variety. Also, the parent lines of hybrid varieties, usually kept as trade secrets, are now often identified with the help of molecular markers and reproduced by other breeders without a license from the rights holder.

· Agricultural products from developing countries sold in the North: Plant variety protection legislation is not yet in place in many developing countries that cheaply produce flowers, food, feed or fuel for the world market.[2] The Northern breeding industry could collect license fees from harvested products imported into Northern countries, where such legislation is well established.

With DNA tests, the variety of the suspect plant material can be identified. Also, DNA tests can often replace plant growing trials. They are feasible on harvested plant material, whether alive (such as seeds, fruits or flowers) or dead (such as soybean flour).[3] In contrast, field tests are limited to living material.

Some Requirements for DNA Based Enforcement

DNA fingerprints are already used in private dispute settlements, especially in order to detect plant varieties that are "essentially derived," i.e. they are very similar to an already protected variety.[4] However, if rights owners wanted to enforce plant breeders' rights titles in court cases on the basis of DNA fingerprints, they would need special provisions:

1. DNA analyses of a seed or plant tissue sample have to be compared with the DNA-based variety description in order to be of legal value.[5] UPOV has a variety description system in order to grant intellectual property rights, but DNA fingerprints are not part of it in most UPOV member countries. They would have to be added to the official variety description so that they could be used for enforcement in court cases.

2. For every crop species, an officially agreed upon set of reference varieties is needed for comparison with the variety in question, and DNA data must be available for all of them.[6] Reference variety collections exist in UPOV member states, but they would have to be completed with large sets of DNA and DNA data collections if DNA fingerprints are to be used to compare varieties. Some industry associations expect UPOV and its member states to set up and maintain DNA databases and continuously develop DNA reference sets, in addition to the current field test system.[7]

3. Sampling must be organised in specific ways – e.g. by an independent person – for the courts to accept the evidence.[8] Seed sampling by customs authorities in the market, and the associated testing, is regulated by different organisations. UPOV has started collaboration with international seed quality and seed test standard-setting bodies. On the invitation of UPOV, a joint meeting took place in November 2014 with the International Seed Testing Association (ISTA) and the Organisation for Economic Co-operation and Development (OECD) Seed Schemes.

OECD and ISTA define seed quality and testing

The OECD is formed by 34 Northern states and, among other things, it develops standards for seeds, in order to make sure – simply put – that seed packets contain the variety mentioned on the label, and that the seed is healthy and has enough germination capacity. The OECD Seed Scheme includes a growing number of developing countries.

ISTA is an association of industry and research organisations developing protocols for testing seeds – again to put it simply – to check whether they comply with OECD seed standards. ISTA also has standard protocols for sampling, for use by customs and other authorities, which could be extended to include requirements for DNA-based enforcement. ISTA's Secretary General, Benjamin Kaufman, is a strong proponent, since up until 2013 he managed the DNA Laboratories of Dupont Pioneer, a world market leader in GMO maize and other biotech products. He has years of experience on ISTA's GMO Task Force.

The quality definitions of ISTA and the OECD, and the associated certification, refer to the seed or planting material, not the variety. Whether a variety has useful characteristics for the farmers is not the concern of the OECD, ISTA or UPOV. Such criteria ("Value for Cultivation and Use" - VCU) are set in some countries and for some crops by variety registration rules for admission to the market, in addition to the DUS (distinct, uniform, stable) criteria. The DUS criteria are applied to varieties for both intellectual property rights legislation and market admission legislation.

Paving the Way at UPOV

The relevant body at UPOV is the Working Group on Biochemical and Molecular Techniques and DNA-Profiling in Particular (BMT). Its November 2014 meeting in Korea was open to all experts, but was attended by only two dozen individuals apart from host country representatives. It called for DNA fingerprints to identify varieties in DUS tests, so that DNA fingerprints would be included in official variety descriptions. The report leaves open whether the current field test methods based on the physical appearance (phenotype) of the plant should be considered as the basis, or as an alternative.[9] That way, the ground is prepared for an apparent compromise in order to accept both, while the real point is to gain acceptance of DNA fingerprints.

In the case of mutations, a flower or fruit can change its colour by mutating a single gene; this is hard to detect in DNA tests with a set of molecular markers that can never cover all genes.[10] This case is cited to calm alleged concerns that field tests

could be replaced by DNA tests (phenotype vs. genotype). However, the real worry is the additional burden of DNA tests (phenotype plus genotype).

This could be an expensive step for UPOV member states. DNA databases of reference variety collections would have to be established: In DNA fingerprinting, a set of molecular markers is applied to compare the sample in question to the DNA of reference varieties. The fact that the cost per DNA analysis is constantly decreasing is of little help, since hundreds of analyses must be carried out to compare the sample in question with the set of reference varieties, and laboratories require constant investment to keep up to date. UPOV members do not need to maintain national laboratories, but they do need to maintain a substantial additional test system, comparable to the field test system with guidelines for each crop species and international working groups in UPOV.

Most member states would not develop national expertise, but instead would leave it up to a few countries as well as the EU to deal with the DNA test system, and thus surrender the knowledge basis for decision-making in order to lower costs. The industry associations are likely to take over; the International Seed Federation has already defined a set of 3,072 molecular markers for maize.[11]

GMO seed companies would be the first to benefit: The molecular markers applied to introduce an additional gene can also be used to detect it for rights enforcement purposes ("characteristic-specific molecular marker"[12]). For enforcement of GMOs, DNA data from a set of reference varieties is not necessary, but including the DNA in the variety description is essential if courts are to be involved.

At its November 2014 meeting, UPOV's relevant working group (BMT) agreed that UPOV should intensify its work on variety description based on DNA fingerprints,[13] and that member countries would need molecular data for the varieties in their reference collections.[14] The agenda of its next meeting scheduled for 2016 was set accordingly. This seed industry-friendly agreement was subsequently approved by UPOV's Technical Committee as well as the Consultative Committee at the UPOV spring session in 2015.

Paving the Way at ISTA and the OECD

At the joint UPOV/ISTA/OECD meeting in Korea in 2014, ISTA and the OECD noted that their requirements regarding DNA markers – i.e. the level of precision of variety identification, which is mainly based on the number of molecular markers – are much lower than those of UPOV.[15] In the case of GMOs, there is just one molecular marker needed to identify the suspected plant material.

The OECD Seed Scheme is expected to include DNA fingerprints in its testing system on a larger scale, to assist the seed industry with enforcement of its intellectual property claims. OECD members questioned the cost of the much higher number of molecular marker analyses required for the plant variety protection purposes of UPOV.[16] It was, however, clarified that common databases for the molecular description of varieties would be useful,[17] and that for each crop, a minimum set of reference varieties should be defined, following the example of maize set by the International Seed Federation.[18] Also, the proficiency of laboratories at national levels was an issue, as only a few may be able in the long run to keep up with new technologies and knowledge.[19] Resource-poor countries would certainly be at a disadvantage.

Although very different levels of precision of DNA fingerprints are required, DNA databases of reference varieties are an issue that UPOV considers a promising field of cooperation with ISTA and the OECD.[20]

Breeders' Rights: Public but Secret?

The parent lines of hybrid varieties are usually kept as trade secrets, and they would have to be publicly disclosed in court cases. The same is true for DNA fingerprints. Disclosure bears the risk of infringements. Therefore, some industry associations maintain private dispute settlement mechanisms, and licensees often have to agree to resolve possible disputes outside of courts.[21] The industry associations are asking UPOV and its member states to allow the use of anonymised private dispute settlement results in court cases. Civil society organisations warn that courts – for example in developing countries – would be influenced by the perceptions of Northern market leaders.[22]

Breeding industry representatives also demand confidentiality for DNA fingerprint data and material.[23] Civil society observers consider this highly questionable from a legal standpoint. Alleged infringers, including farmers, would not have access to information until they are taken to court.

DNA fingerprints are often trade secrets. Can such trade secrets become part of public DUS Test Guidelines? In their laws, UPOV member countries require publication of variety descriptions,[24] which is a clear contradiction.

With regard to ownership of DUS samples and of DNA and DNA data during and after the DUS tests, there are conflicting aims and principles regarding intellectual property rights on the one hand, and trade secrets on the other. Intellectual property such as patents or plant variety protection rights titles are subject to an obligation to publish. Patents or PVP titles cannot cover trade secrets. Title owners or applicants

must decide between the two, and can't enjoy the advantages of both while rejecting any disadvantages. There is no point in strengthening confidentiality of DUS test samples and DNA and DNA data if such data then have to be used in courts against alleged offenders.

If molecular data are used to enforce plant breeders' rights, farmers and other breeders need access to these data to defend their cases. Apart from cost and technical problems, confidentiality rules with regard to DNA-based variety descriptions may prevent alleged infringers from accessing the necessary data to defend their cases.

The BMT, however, agreed that it would be useful to harmonise confidentiality rules regarding plant material and DNA data stored in the examination offices of its member states.[25] There is a resulting push for revising test guidelines as well as the relevant Technical Guidance Protocols (TGP/5[26] and TGP/15[27]) and other crucial UPOV documents (INF/15 on cooperation between UPOV members[28]). Almost as a matter of course, higher UPOV bodies agreed to follow up on the industry-driven plans at their spring 2015 session.

Conclusions

With the ten largest companies controlling three-quarters of the commercial seed market, global market power is already among the most concentrated in the agricultural value chain. Seed and planting material market leaders aim at further increasing their income from royalties in major ways.

1. Least Developed Countries are cornered to pay license fees for exports to the North

A substantial royalty income could be tapped from those developing countries that do not have intellectual property legislation for plant varieties, but that grow agricultural products to be sold in the North. DNA fingerprinting can be used to identify the variety from which the harvested product has come. Least Developed Countries enjoy a transitional period that exempts them from WTO intellectual property obligations. The resulting cost advantage would be rendered obsolete if license fees are charged on their exports.

2. Intellectual property rights are unrecognisable to seed users

DNA fingerprints can identify the variety of suspected seed, often replacing plant growing trials, and fingerprinting can be performed even on processed food or feed. Some industry associations want to keep DNA fingerprints as trade secrets, so that

users of seed or planting material or processed food or feed would not have access to information before being taken to court, and not be able to detect IP-protected seeds or plants in their fields In addition, these associations want courts to follow industry standards.

3. DNA-based enforcement goes beyond UPOV Conventions

According to the UPOV Conventions, member states already have to provide legal remedies for effective enforcement of plant variety rights. Yet in addition, and going beyond the UPOV Conventions, some industry associations are pushing UPOV and other international organisations, as well as customs authorities, for costly technical and questionable legal provisions at the international level in order to extend enforcement based on DNA fingerprints.

Endnotes

[1] For example, in Japan: BMT/14/6 and BMT/14/6 Add Rev (presentation by Hiroshi Goto). Since 2004, out of 170 infringement cases in Japan, 110 involved a similarity test using a DNA variety identification technique. The Japanese PVP Office (NCSS) has since preserved about 3,000 DNA samples of protected varieties. The Netherlands PVP office (Naktuinbouw) and the French Group for the Study and Control of Varieties and Seeds (GEVES) offer DNA-based variety identification services.

[2] Least Developed Countries are exempted until 2021 from the WTO TRIPS Agreement obligations to provide intellectual property legislation. See also Berne Declaration/Econexus (2014) AGROPOLY - A handful of corporations control world food production

[3] BMT/14/Joint/3 Rev. "DNA-Based Methods for Variety Testing" made at the OECD/UPOV/ISTA Joint Workshop on Molecular Techniques. Benjamin Kaufman, Secretary General, The International Seed Testing Association (ISTA)

[4] International Seed Federation: Regulation for the Arbitration of Disputes concerning Essential Derivation

[5] BMT/14/Joint/6 The OECD Seed Schemes (presentation by Gerry Hall), p 19

[6] BMT/14/20 para 22

[7] ISF View on Intellectual Property. Adopted in Rio de Janeiro, Brazil, 28 June 2012, p.13; Monsanto holds that molecular markers can be useful "as a reference DNA fingerprint that functions as part of a plant passport, additional to the variety description", see http://www.upov.int/edocs/mdocs/upov/en/bmt_13/bmt_13_19.pdf; CIOPORA favours inclusion of molecular markers in variety descriptions, DUS tests and enforcement on a voluntary basis, see Working Group on Biochemical and Molecular Techniques, and DNA-Profiling In Particular Thirteenth Session Brasilia, November 22 to 24, 2011. The Use Of Molecular Techniques For Plant Variety Protection – Approved Position of Ciopora (AGM, Rome, 12th April, 2011). Document prepared by the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Plants (CIOPORA)

[8] BMT/14/6 and BMT/14/6 Add Rev (presentation by Hiroshi Goto). In Japan, where varieties are described by DNA fingerprints, non-government official staff members of the plant variety office ("G-men") are advising seed companies on how to correctly take samples so that courts would accept cases. They should not have investigative authority.

[9] BMT/14/20 para 48

[10] See also UPOV FAQ "varieties which have a large phenotypic difference may have the same DNA profile for a particular set of molecular markers (e.g. some mutations)."

[11] BMT/14/7 Rev Identification of SNP Markers to Aid Assessment of Essential Derivation in Maize. Document prepared by experts from International Seed Federation; ISF Guidelines for Handling Disputes on Essential Derivation of Maize Lines. ISF 2014

[12] The example given by the relevant UPOV Technical Guidance document is a herbicide-tolerant GMO maize. UPOV Document TGP/15 Guidance on the Use of Biochemical and Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)

[13] BMT/14/20 para 22. The BMT agreed that this should be considered further by the Technical Committee, bearing in mind that it was not covered by an existing model in document TGP/15

[14] BMT/14/20 para 22

[15]BMT/14/Joint/3 p17 (presentation by Benjamin Kaufman, ISTA) and BMT/14/20 para 47

[16] BMT/14/20 para 55 refers to the OECD Member questionnaire; the rather negative results are not reported here but in BMT/14/Joint/6 p21. (presentation by Gerry Hall, OECD)

[17] BMT/14/Joint/5 p3

[18] BMT/14/20 para 39-40 and Revised Addendum to document BMT/14/5 - The Use of Reference Varieties Distinctness: An Approach under Investigation in the United States of America for Potential Application in Plant Variety Protection. Authors: Paul T. Nelson, Fred Achard, Marymar Butruille, Stevan Madjarac, Monsanto Company, St Louis, MO USA

[19]BMT/14/Joint/3 p10 (presentation by Benjamin Kaufman, ISTA)

[20] BMT/14/Joint/5 p3

[21] Alternative Dispute Settlement Mechanisms http://www.upov.int/edocs/infdocs/en/upov_inf_21_1.pdf

[22] http://www.apbrebes.org/files/seeds/14%2010%202014%20APBREBES%20statements%20CAJ%20AG.pdf

[23]BMT/14/20 para 34-37 and BMT/14/11 Rev Ownership and use of DUS samples and of DNA and DNA data during and after the DUS tests (presentation by Kees van Ettekoven). CIOPORA holds that "Fingerprint data are generally confidential and owned by the holder of the respective variety and can only be disclosed with the owner's permission; a general permission could be granted to the independent examination offices for building databases for their internal use only. CIOPORA is not in favor of disclosing this information to external parties," see Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular. Thirteenth Session Brasilia, November 22 to 24, 2011. The Use of Molecular Techniques for Plant Variety Protection – Approved Position of CIOPORA (AGM, Rome, 12th April, 2011) Document prepared by the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Plants (CIOPORA)

[24] E.g. in the Netherlands, see BMT/14/11 Rev Ownership and use of DUS samples and of DNA and DNA data during and after the DUS tests (presentation by Kees van Ettekoven of the public/private variety examination office Naktuinbow in The Netherlands).

[25] BMT/14/20 para 36

[26] BMT/14/20 para 36

[27] BMT/14/20 paras 22 and 27

[28] BMT/14/20 para 32, para 36 and BMT/14/11 Rev Ownership and use of DUS samples and of DNA and DNA data during and after the DUS tests (presentation by Kees van Ettekoven)