Report Sparring partner group Novelty Protection September 2016 – August 2017

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Actions:
The **activities** of the SPG are shortly numerated by the date on which the action took place and by subject. For those who want to know more details about the subjects please read the specific information per issue in **the notes** below.

- 30 September 2016: Publication of AIPH's short paper **'Abusing Intellectual Property Rights: an explanation of the correct use and abuse of patents in the sector'**. See note 1.

- 24 October 2016: **CNLA publishes** AIPH short paper 'Abusing Intellectual Property Rights' in the CNLA newsletter. Other SPG members are stimulated to publish it in their own national industry journals, newsletters or communications as well.

- 24 October 2016: SPG is informed about **Bayers' take-over of Monsanto**: monopoly and empowerment among the suppliers of genetic material and among retailers as well, is seen increasingly. The growers are in-between! The Bayer-Monsanto concentration is a manifest example of the concentration at the suppliers end.

- 2 November 2016: AIPH contributes an article to the yearly **CIOPORA Chronicle magazine**. A special edition of FloraCulture International, about the subject: 'minimum distances between varieties', written by Mia Buma. See note 2.

- 12 November 2016: SPG is informed about the outcome of the seminar on 18 May 2016, organized by the EU Commission with the theme: **'Finding the Balance: Exploring solutions in the debate surrounding patents and plant breeders rights'**. See note 3.

- 9 January 2017: SPG is informed: Dutch renowned company got an **inspection visit** of the Dutch Food and Consumer Product Safety Authority (NVWA). This authority inspects amongst others compliance with **the legal requirements of 'Nagoya'**. See **note 4**.

- 12 January 2017: SPG is informed about next step in finding the balance between patents and plant breeders rights: the **European Patent Office (EPO)** has decided to put a hold on all proceedings regarding patentability of plants obtained by an essentially biological process. See note 3.

- 30 January 2017: The CPVO requested AIPH to respond to the survey **"Community Plant Variety Office (CPVO) - a Strategic Plan Consultation'**. This represented a good opportunity for AIPH to give its input to the CPVO.

- 16 February 2017: The article **'The world of PBR is alive and kicking!'** with subtitle; 'Reflections on the world of Plant Breeders Rights' is sent to the SPG. See note 5.

- 22 February 2017: AIPH participates in **evaluation Community Plant Variety Office's external Communications**. The CPVO evaluates its external communications. CPVO wanted feedback on its functioning and communicating to its surroundings. Through participation AIPH was able to influence that in a positive way.

- 23 February 2017: SPG is informed: European Commission's view confirmed by the EU member states: **No patents on conventional plant breeding**. The European Member States unanimously confirmed that it was never the intention when drawing up the EU Biotech Directive – which regulates patent protection of biotechnological inventions – to grant patents to products that are the result of an essentially biological process. See note 3.

- 28 February 2017: SPG is informed about **PBR developments in Colombia**. A few growers claimed before Court that the procedure of ICA (the Colombian national authority for the application of plant variety rights) to take over DUS reports from other countries, which are used to grant PBR right to breeders, is invalid. See note 6.

- 17 May 2017: an update of the developments concerning the **Nagoya Protocol** has been sent to the SPG. See note 7.

- 19 May 2017: SPG is informed about the **destroying and withdrawing of genetically engineered (GE) Petunias** from sale because of no GMO authorization. Does destruction of all material GM orange petunias mean all material is excluded? See note 8.

- 24 May 2017: **Pieter van Oost**, who is working for **AVBS**, the Belgian Nurserymen and Growers Federation (AVBS), joins the SPG.

- 30 May 2017: SPG is updated about the **UPOV meetings last April** and about PBR developments in relation to China, because China is celebrating 20 years of PVP (plant variety protection) in China.

- 29 June 2017: **Guido di Primio** participates in the SPG on behalf of Italian member **ANVE**. The SPG receives an update about the concurrence between PBR system and Patent system in the sector. See note 3.

- 5 July 2017: **European Patent Office (EPO) takes decision**: per 1 July 2017 no patentability of plants, which are obtained by essentially biological processes. See note 3.

- 6 July 2017: **AIPH publishes a press release** about EPO's decision.

- 10 July 2017: **AIPH meet Edgar Krieger, the Secretary-General of CIOPORA**, to update AIPH's and CIOPORA's positions and opinions in the field of Intellectual Property (IP) and Plant breeders rights (PBR). Jaap Kras and Mia Buma represent AIPH in this yearly informal meeting. The SPG received the report of this meeting at 26 July 2017. See note 9.

- 16 July 2017: SPG is informed about the **Consequences for PBR rights of the UK** withdrawal from EU (Brexit). See note 10.

Details and further information on the actions:

Note 1:
AIPH short paper '**Abusing Intellectual Property Rights: an explanation of the correct use and abuse of patents in the sector'**
Main message from the paper: Because society benefits from innovation and technical and cultural progress, the monopoly makes an exception to the rules of competition and the free

market forces that normally apply. But, the monopoly positions may never lead to restricted or unlawful competition between market parties and forces. The monopoly position and the way the IP owner does use it, have to be in balance!

Note 2:
CIOPORA's Chronicle magazine 2016
To read CIOPORA's Chronicle magazine is highly recommend as it gives a clear overview of several aspects of the PBR system, which have to be improved. CIOPORA gives solutions for that in its Position Papers on PBR, which were completed in 2016. The 2016 edition contains the key issues relating to the current state of worldwide PBR. AIPH contributed by an article written by Mia Buma about the subject: minimum distances. (See further details below).
Further in the Magazine, articles are published about the following hot issues:
European trademarks and variety denomination; the effects and compliance rules of the Nagoya Protocol should not relate to commercially available plant varieties; minimum distances between varieties.

Note 3:
'Finding the Balance between Patents and Plant breeders rights': exploring solutions in the debate surrounding patents in relation to PBR.
As an outcome of the EU seminar (which took place 18 May 2016) the EU Commission published in an interpretative note the following important conclusion: 'The EU Biotechnology Directive addresses the patentability of plants and animals, specifically excluding plant and animal varieties from the scope of patentable subject matter (see Article 4 of the EU Biotechnology Directive98/44/EC). It also establishes that 'essentially biological processes for the production of plants and animals' are not patentable'.

<u>Consequences for Horticulture</u>
For the horticulture industry this publication of the interpretative note on the EU Biotechnology Directive is positive, as it clearly defines that 'essentially biological processes for the production of plants and animals' are not patentable.
The SPG was informed that this interpretative note can be useful, but its value depends how it will be effectively used by judges, by the legislators in the EU Member States and the European Patent Office (EPO). The information in an interpretative note does not have the status of law and is not enforceable.
The effect of the interpretative note was that the practice of the European Patent Office's (EPO) examination came under discussion. So EPO decided to put a hold on all proceedings before the EPO in regard to patentability of plants obtained by an essentially biological process.

In February 2017 the European Commission's interpretative note was confirmed by the EU member states: No patents on conventional plant breeding. They indicated that it was never the intention when drawing up the Biotech Directive to grant patents to products that are the result of an essentially biological process. The industry was happy with this result. The news contributes greatly to the free access to biological material, which stimulates the necessary innovation in the industrial sector.
The next step was how EPO would fulfil this agreement between the EU member states. About 200 plant patent applications were waiting to be granted by EPO.

In July 2017 implementation of the EU-definition took place into the regulation of EPO
EPO is an independent institute (is not an EU-institute) and therefore governed by its own regulations. The EU-members within the Convention were in favor that EPO adapts the definition of the EU Commission that 'biological processes for the production of plants and animals' are not patentable. In the same month all the EU-members of the European Patent Convention agreed with this definition. As a consequence, EPO changed its legislation and

policy to no longer grant patents on plants. EPO agreed as well, from then on, that products resulting from cross-breeding or other classical breeding methods, cannot be granted patents. Where patents have already been granted on plants and plant characteristics these will continue to exist.

Will plants not be patentable after the implementation by EPO?
We can't be sure about the effects of the new EPO legislation, implementing rules and the effects for the existing patents on plants. Certainty that EPO will not grant patent applications on plants, will be gained after the concerned juridical courts have approved that the definition of the EU-Commission (that 'biological processes for the production of plants and animals' are not patentable) is correct. The decisions of EPO can be brought before the court, and it is very likely that will be happen. There is a big chance that large breeding companies, who are in favor of using the patent system to protect breeding results, will go to court.
And still then, the discussion about the concurrence between the Plant breeders rights system and the patent right system won't be solved completely, as with the upcoming new breeding techniques, like intragenesis, cisgenesis and CRISPR-cas, the relevant intellectual property systems PBR and patent right have to be adapted again in the future.

Finally
These developments do show nicely how legislation is always in development, not because lawyers like it, but just because the world is the playing field of the horticultural sector and this large world is very innovative and therefore does regularly change horticultural economies and legislations!
Several authorities as well as the agricultural and horticultural industries, who have lobbied for this since 2010, made clear they were very content with EPO's decision that no more patents will be granted to classical breeding products. As known to AIPH, the use of patents limits the breeders' free access to genetic material, as they've got to ask for permission from the relevant patent holder. That's a change from the Breeders' Rights system, which stipulates that breeders almost always have free access to each other's cultivars. The main argument against the use of patents is that they hinder innovation and that they decrease biodiversity.

Still some concerns
Still the sector does have some concerns that this decision may not be the final step to ensure that no patents will be granted to plants. There are several reasons for concerns: for the big breeding companies, who own many patent claims on plants, there are enormous financial implications and therefore they will probably try to find ways to slip through the net of the law. Secondly, the already granted patents on plants and plant characteristics will continue to exist. Finally, EPO's decision creates clarity for its 38 European member countries, but it does not reach a worldwide solution.

Note 4:
Inspection visit of the Dutch Food and Consumer Product Safety Authority (NVWA) -compliance with **the legal requirements of 'Nagoya'.**
NVWA is the Dutch authority, which monitors the safety of food and consumer products and enforces nature regulation. The authorities' goal is to safeguard human and animal health and welfare.
The inspected Dutch company were surprised at the manner in which the officials carried out the audit and it became clear that they did not understand the content of the Nagoya regulations. Therefore the officials asked the director whether the Nagoya Protocol was known to the company and how it handles import of genetic material.
At the time the company had put on record an inventory of its genetic material at the notary to respond to the 'Nagoya liabilities'. In response to the NVWA officials the company has presented its well-kept 'Nagoya documentation' and after inspection of these documents the inspectors left.

Note 5:

'The world of PBR is alive and kicking!'

The article 'The world of PBR is alive and kicking!' with subtitle: 'Reflections on the world of Plant Breeders Rights' is written by Kees van Ettekoven for the occasion of his retirement after 35 years as head of the Variety Testing Department of Naktuinbouw (Dutch Horticulture Inspection Service). His paper gives a helicopter view of how innovative and international the PBR world is. Kees mentions interesting PBR aspects in relation to China, India, the USA and Japan. CNLA published the article in its newsletter.

Note 6:

PBR developments in Colombia.

A few growers claimed before Court that the procedure of ICA (the Colombian national authority for the application of plant variety rights) to take over DUS reports from other countries, which are used to grant PBR right to breeders, is invalid. As an argument for this invalidity they refer to rules of the Andean Community of Nations. This is comprising the South American countries of Bolivia, Colombia, Ecuador and Peru. For that reason the opponents claim that the granted Colombian PBR rights are not valid and thus have no status on which an inspection or test could be exercised.

Note 7:

The Nagoya Protocol: Meaning and consequences of the Nagoya Protocol in a nutshell.

Meaning

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (ABS) is a supplementary agreement to the Convention on Biological Diversity. It provides a legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

The Nagoya Protocol on ABS was adopted on 29 October 2010 in Nagoya (Japan) and entered into force 90 days after the fiftieth instrument of ratification. Its objective is the fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity.

Consequences

The consequences of Nagoya cause not only significant additional costs and administrative burden, they also conflict with the UPOV provisions of the so-called 'Breeder's exemption', which means that all existing source material is available at no charge to anyone for the purpose of breeding. In other words, plant breeding can only proceed if genetic material is freely available for breeding new varieties. Without genetic resources there will be exponentially fewer new varieties!

The importance of 'Access and Benefit Sharing' is endorsed by the horticultural industry with respect to propagating material. The industry has always realized this and has played an important role in maintaining genetic resources. The breeder's exemption means a huge contribution to biodiversity and is also recognized as such in the IT PGRFA (International Treaty on Plant Genetic Resources for Food and Agriculture). Horticultural companies make an important contribution to maintaining genetic resources, to multiply and to describe them (think for example of their contribution to the Centre for Genetic Resources Netherlands (CGN). The companies supply -either individually or together, make major contributions to various developments related to genetic sources.

The rules for the exchange of genetic material should be simple and practicable, with the 'freedom to operate' guaranteed as much as possible. However, as a result of the "access to the Nagoya regulatory genetic material" the issue has become quite complex. The risk of restricted access to genetic resources is to inhibit innovation and reduce genetic diversity. Access to genetic resources is also essential to ensure that the sector can continue to contribute to sustainable agriculture and horticulture.

Two practical consequences of the Nagoya Protocol have to be kept in mind:
- Every country has to establish a competent authority who is responsible for the access and benefit sharing arrangements of the genetic resources over which it has sovereign rights. If a breeder wants to access a genetic resource in a certain country he has to obtain the permission from that authority, or to put it in the official terms: he has to obtain Prior Informed Consent and Mutually Agreed Terms, unless this is waived by the authority.
- If a breeder develops a new variety he has to be able to prove that the breeding materials used to create to the variety, have been obtained in a proper manner, i.e. fulfilling the access and benefit sharing obligations of the country where the breeding materials came from. For example, proof may be asked for with Intellectual Property applications (think of plant breeders rights), market approvals or possibly also trans-border movement of products.

It is clear that these consequences are a threat for the breeders exemption provision in the UPOV Plant variety rights system, as a breeder may have to provide information on the commercial varieties used as a parent in breeding, information that the breeder of the parent variety has. This creates obligations that UPOV explicitly excludes in the breeder's exemption.

<u>AIPH's position</u>
Therefore, it is AIPH's opinion that the implementation of legislation relating to access to genetic sources, is threatening to create unacceptable barriers to plant breeding by implementing retroactive effect and the obligation of eternal data storage. Furthermore, the breeders' exemption is undermined. This will lead to reduced use of the new genetic sources, which may hamper progress in product quality, yield potential and sustainability of crops. This is why the access systems for genetic sources in plant breeding should combine broad access with light regulatory pressure and a high degree of legal certainty for those using genetic sources and making them available. It is equally important to continue enforcing the widely used breeders' exemption without any supplementary obligations. So, workable rules are necessary!

Besides, it should be recalled that the CBD was negotiated and adopted with the view of finding answers to and preventing the loss of biological diversity and to ensure the conservation of nature via the conservation of biological diversity and the sustainable use of its components. Thus, the CBD is clearly an instrument to address the conservation of natural resources. In conclusion, commercialized varieties are not within the scope of the CBD and thus, not in the scope of the Nagoya Protocol.

Commercialized varieties are neither existing within ecosystems and natural habitats, nor their distinctive properties are primarily shaped by specific environmental conditions in a given country. Starting to develop a new variety a breeder crosses a great range of different plants to create high genetic diversity. He then tests the characteristics of all the different plants in different environments in different countries or greenhouses and in laboratories as well. The breeder actively creates, evaluates and selects plants and creates the distinctive properties of the final plant which becomes a variety. Even after commercialization the breeder has according to European law to ensure that the variety keeps its distinctive properties as described for variety registration. Thus, in contrast to natural resources, commercial varieties are man-made creations where the distinctive properties are created by the breeder.

Note 8:
GMO Petunias
In May 2017 the Finnish Food Safety Authority Evira had decided to remove from sale seeds and planting stock of the ornamental plant Petunia characterised by the orange colour of the flowers which had been produced by means of genetic engineering. Genetically modified varieties of Petunia are not authorised for cultivation in the EU. As a result of this, companies

and institutions destroyed all the material of the Petunia plants. The seed lot and any plants, delivered for further growing on, have been recalled from production. The companies were ordered by the authorities to show their crossing history and at the end everything seemed to point to "unintentional GMO". By the way, GM Petunias do not cause any risk to people or the environment.

Or did they? That's what the matter hinges on. Orange Petunias have been put on the market, so it cannot be excluded that the material used, originated from GMO material which was developed already in 1987. It is possible that someone - anywhere in the world - who was not aware of the GMO program became very excited about the orange Petunia and started to breed using that GM material, assuming it hadn't been destroyed.
Current status: we do not know how the GMO material came on the market.

Note 9:
AIPH meets Edgar Krieger, the Secretary-General of CIOPORA (10 July 2017)
Goal of the informal meeting is: to determine AIPH and CIOPORA's common positions and statements concerning IP and PBR and help each other to support the mutual interests at the relevant platforms (think of lobby at national and international authorities (for example UPOV, information supply to member organisations and to magazines in the industry etc.).
The issues which were discussed:
-World Flower Summit November 2017 (at IFTF)
-Mutual affiliated membership CIOPORA and AIPH
-PBR developments in Colombia
-Brexit
-Decision of EPO RE: patent on plants
-Nagoya
-Minimum distances between varieties
-Developments within CPVO: if a dispute arises in Court on the question whether a variety is infringing the PBR of another variety for not being distinct, currently the Court regularly asks the examination office, that made the DUS examination of the supposedly infringing variety, to act as expert. It might be more smart and fair that another testing station should do the testing because of the wise rule: the butcher should not control its own meat. So for example, if the Naktuinbouw (NL) did the DUS testing, the Bundessortenamt (Germany) should do act as expert in an infringement case before a Court.

Note 10:
Consequences for PBR rights of the UK withdrawal from EU (Brexit)
The UK leaving the EU is currently calculated to be March 30, 2019. What will happen to the validity of the EU community plant variety titles in the UK?
What will happen to the role of the examination offices in the UK, who play a crucial role in the DUS examinations for plant varieties? The main examination office for ornamentals in the UK is NIAB, a highly qualified DUS examination office. For 678 species, mostly ornamentals, NIAB is the entrusted examiner of the EU Community Plant Variety Office (CPVO).

<u>Solutions to minimize negative consequences</u>
CIOPORA informed AIPH about their talks with the EU Commission on Brexit. The Commission listens to our industry and is willing to support to some extent and to minimize the negative consequences of the Brexit.
They understand that it must be avoided that after 30 March 2019 varieties are no longer protected in the territory of the UK and expressed their intention to work for a solution. However, it is mainly up to the UK to convert the titles into UK titles.

<u>Exchange of thoughts in the SPG</u>

AIPH keeps in mind that not only the breeders, but also the growers would not appreciate it if varieties, which are protected in the EU are not protected in the UK anymore after 30 March 2019.
Likewise, not only the breeders but also the growers would be supportive to the quality of DUS examinations. AIPH keeps also in mind that this situation will not only affect the EU members, but also will affect the non EU AIPH members. For example, non EU countries are also using the DUS reports from NIAB (the UK testing station) for their own national PBR applications.
Action: a AIPH resolution of the issue is prepared to circulate these to the SPG for comment and then circulate to all members in advance of the General Meeting where support can be confirmed. This would be followed by a press statement and other actions as approved by the members.