



CropLife International A.I.S.B.L.
Avenue Louise 326, box 35 - B-1050 - Brussels - Belgium
TEL +32 2 542 04 10 FAX +32 2 542 04 19 www.croplife.org

Howard Minigh
President & CEO

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to the attention of:

Minister G. Verburg, Ministry of Agriculture, Nature and Food Quality
Minister M.J.A. van der Hoeven, Ministry of Economic Affairs
Minister Dr. E.M.H. Hirsch Ballin, Ministry of Justice

Dear Sirs,

Headquartered in Brussels, CropLife International (CropLife) is a global plant science industry federation and network of regional and national associations in 91 countries.

CropLife has learned that the Dutch plant breeders association, Plantum NL (Plantum), has communicated a position which advocates strong opposition to patent rights on plants.ⁱ The Plantum position states that, "*free availability, use and exploitation should not be allowed to be obstructed in any way, either directly or indirectly, by patent rights.*" This policy would preclude patentees from exercising any of the rights associated with their invention. This new Plantum position – which was opposed by all CropLife member companies who are also members of Plantum – is inconsistent with international, regional, and national legislation and policies.ⁱⁱ

CropLife understands the concerns of some breeders who view patented trait technology (PTT) in seed as an impediment to their ability to conduct further breeding. However, these fears are not grounded in precedent; experience shows that patent protection does not have a negative effect on the development of new and improved germplasm. Breeders in nations without a breeders' exemption in their patent laws, such as the United States, are among the most successful in the world. CropLife believes that a balanced solution that addresses the concerns of all parties in this matter is required. The purpose of this letter is to help move toward such a solution.

Global Developments: The present global challenges demand immediate and intensive agricultural science and technology innovations.ⁱⁱⁱ Decreases in the amount of arable land available for agriculture, combined with limited water supplies and increased seasonal drought underscore the urgent need for innovative agricultural technology. For farmers facing these considerable challenges the need has never been greater.

Research and Development: CropLife member companies are global leaders in the continuous research and development (R&D) of plant science solutions to answer these global food demands in sustainable ways. Modern science methods include cellular and molecular biology techniques including: genome and proteome research, gene mapping, marker-assisted breeding and hybridization technology. Utilizing these techniques to produce a new plant-science invention is a lengthy and costly process, with seed companies investing a significant percentage of their current sales in R&D. Be it genetically modified or traditionally developed plants, developing a new plant invention often requires decades of funding and hard work. Yet, the result of a new invention in plant sciences is a simple product: seed. Without effective and enforceable intellectual property (IP) rights, the unauthorized propagation of plants containing PTT prevents breeders from achieving the return on their investments necessary to continue R&D.

IP Rights: The need to protect plant related inventions from infringement has been recognized in IP legislation as early as the 1883 Paris Convention. Today, World Trade Organization (WTO) member nations are guided by their obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to protect plant varieties by patents, a unique or one-of-a-kind plant variety protection (PVP) system, or a combination of the two.^{iv} PVP is suitable to protect overall improvements in plant germplasm typically associated with the results achieved using traditional breeding, but is not effective in protecting a specific trait or gene.^v Any such gene or trait could be accessed by competitive breeders and transferred by traditional crossing with other varieties under the PVP statutory breeders' exemption. Further, PVP does not provide any protection for innovative methods of breeding (e.g. marker-assisted breeding). The results of modern plant research and breeding cannot be adequately protected solely by PVP, but rather require a combination of both patents and PVP.

The Plantum position acknowledges that "[d]eveloping a new plant variety requires investments," which requires protection by intellectual property rights. However, Plantum believes that such protection can be achieved solely by PVP. The Plantum view ignores the advancement of plant science and the increasing importance of trait research.

TRIPS Agreement and Exceptions to Patent Rights: The Plantum position is not only biased against certain research-focused plant breeders, but it also does not comply with TRIPS standards. Article 30 of the TRIPS Agreement provides that exceptions to patent rights (1) must be limited, (2) should not provide unreasonable conflict with normal exploitation of the patent, and (3) should not unreasonably prejudice the legitimate interests of the patent owner while taking into account the legitimate interests of third parties.

The Plantum position clearly conflicts with "*the normal exploitation of the patent*". Further, under the Plantum position, patents in the plant breeding sciences would receive significantly weaker protection than that extended to other patents in biotechnology or in other fields of science and industry; thereby, the Plantum position would "*unreasonably prejudice the legitimate interests of the patent owner.*"^{vi}

Inconsistency with European and National Patent Law: Patents can be granted under the European Patent Convention (EPC) for plants and seeds if they fulfill the requirements of patentability and the claims are not restricted to a specific variety.^{vii} These provisions have fostered innovation in genetically modified plants as well as plants improved by modern breeding processes (such as marker-assisted breeding) in Dutch plant breeding^{viii} and throughout Europe. The national laws of many member-country adherents to the EPC contain a statutory research exemption; not to be confused with a breeders' exemption.^{ix} In particular, Article 53(3) of the 1995 Patent Law of the Netherlands provides that "*The exclusive right shall not extend to acts solely serving for research on the patented subject matter*". However, research on the patented subject matter does not permit the development or commercialization of new plant varieties containing the patented subject matter as is suggested by the Plantum proposal.

EU Biopatent Directive: The Plantum proposal also exceeds and contradicts the European Union Biotech Patent Directive 98/44/EC.^x The Plantum proposal would result in an inventor's inability to exert his or her patent rights when the invention is contained in seed, contrary to Recital 46 of the Directive, which states: "*Whereas, in view of the fact that the function of a patent is to reward the inventor for his creative efforts by granting an exclusive but time-bound right, and thereby encourage inventive activities, the holder of the patent should be entitled to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the use of patented, non-self-reproducing products, that is to say the production of the patented product itself.*"

The Plantum proposal further conflicts with the Directive's objective to guarantee EU harmonized protection of biotechnological inventions. The proposal would establish significant

differences in legal protection for biotechnological inventions and lead to distorted competition and trade.^{xi}

Plantum Proposal: Plantum suggests an extensive breeders' exemption which is not at all contemplated in the EPC, the TRIPS agreement, or the EU Biotech Patent Directive. The Plantum proposal not only argues to exempt the use of patented plants for breeding, but also for the development and commercialization of new varieties comprising the patented element. The Plantum position is a *de facto* expropriation of the patentee: every patent granted on plants would be unenforceable and thus rendered useless against competition. Such expropriation under the Constitution of the Netherlands is admissible only if there is public interest and if a compensation is paid.^{xii} Both prerequisites are not given - CropLife does not see an argument for a general public interest to abandon patent rights for plant breeding.

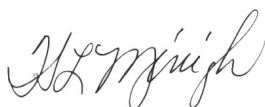
Were the Plantum position to be implemented, companies would be denied any incentive to invest into research and development of traits and other plant related inventions. In consequence, CropLife believes that the Plantum position would have a severe chilling effect on innovation. Plantum argues that the lack of a breeder's exemption in patents may limit access to genetic resources, and *"that open, continued innovation, which has been so characteristic of plant breeding until now, is hampered by this."* CropLife believes that this is incorrect, and that more balanced, tailor-made solutions are available to avoid any limitations patent elements may have on the available germplasm base.

A Balanced Breeders' Exemption: It is CropLife's view, that any breeders' exemption must balance reasonable access to the genetic background of a plant without diminishing the rights of the inventor. CropLife companies are prepared to provide the government of the Netherlands whatever assistance it may request to develop a solution which meets the interest both of the PTT innovators and traditional breeders. CropLife suggests the government of the Netherlands consider an approach that strikes a reasoned balance in which breeders may freely, without a license, use germplasm containing PTT for developing and commercializing a new variety that does not contain the PTT under the conditions that 1) the PTT-containing material is discarded as soon as practically possible and in compliance with all applicable laws and regulations and 2) continued breeding occurs only with PTT-free germplasm. CropLife believes that this proposal for a balanced breeders' exemption prevents a restriction of the germplasm base available for further breeding under PVP without unduly diminishing the rights of the patentee with respect to the PTT.

Conclusion: The government of the Netherlands should not adopt or support the anti-IP rights position proposed by Plantum, but rather craft a balanced position which takes into account the interests of inventors.

Plant breeding is a major global industry and very important to the Netherlands. The total value of the commercially traded seed amounts to globally approx. U.S. \$30 billion.^{xiii} More importantly, plant breeding is absolutely critical in our attempts to overcome the serious global development and environment challenges we face today. Given that today's global economic downturn already threatens to decrease investment in innovative agricultural science R&D, it is clear that any effort that will result in reduced plant science innovation could likely have devastating consequences.

Sincerely,



Howard Minigh

END NOTES

- i Plantum NL position on patents and plant breeders' rights; adopted 6 May 2009; "This position is as follows: 1. Biological material protected by patent rights should be freely available for the development of new varieties. 2. The use and exploitation of these new varieties should be free, in line with the 'breeders' exemption' of the UPOV Convention. 3. The aforementioned free availability, use and exploitation should not be allowed to be obstructed in any way, either directly or indirectly, by patent rights."
- ii ISF (International Seed Federation) View on Intellectual Property, Bangalore 2003: ISF considers that a commercially available variety protected only by Breeder's Rights and containing patented elements should remain freely available for further breeding. If a new plant variety, not an essentially derived variety resulting from that further breeding, is outside the scope of the patent's claims, it may be freely exploitable by its developer. On the contrary, **if the new developed variety is an e.d.v. or if it is inside the scope of the patent's claims, a consent from the owner of the initial variety or of the patent must be obtained.** [Emphasis added]
- iii "The world's population is projected to increase from 6.7 billion in 2006 to 9.2 billion by 2050. The absolute number of undernourished people has grown to 963 million. Nearly 10 million people still die each year of hunger related diseases. Environmental challenges such as climate change, water scarcity, invasive pests, and land degradation have accounted for a 25% loss of the world food production during this century." United Nations Environment Programme, "The Environmental Food Crisis," 2008.
- iv TRIPS Art. 27 b (3): "Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."
- v Any such gene or trait could be accessed by competitive breeders and transferred by traditional crossing with other varieties under the PVP statutory breeders' exemption.
- vi TRIPS Art. 30: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."
- vii The requirements for a patent under the European Patent Convention are novelty, inventive step and industrial applicability.
- viii The table below represents a selection of patent applications resulting from plant related research and breeding in The Netherlands (without prejudice to the patentability, validity or enforceability of these patents). A significant part of the patent applications resulted from research in medium size enterprises. More detailed information can be obtained from the European Patent Office (http://ep.espacenet.com/?locale=en_EP).
- | Patent No. | Filing Date | Patentee | Title |
|------------|-------------|---------------|--|
| EP1763991 | 2007-03-21 | Rijk Zaan | red lettuce |
| EP0942643 | 1999-09-22 | Rijk Zwaan | multileaf lettuce |
| EP0921720 | 1999-06-16 | Rijk Zwaan | aphid resistance in composites |
| EP2041289 | 2009-04-01 | Enza Zaden | resistance to powdery mildew and absence of necrosis in cucumis sativus |
| EP1613145 | 2006-01-11 | Enza Zaden | method for obtaining fruits of the genus capsicum with improved taste and enhanced nutritional value |
| EP1179089 | 2002-02-13 | Enza Zaden | method for obtaining a plant with a lasting resistance to a pathogen |
| EP1998608 | 2008-12-10 | Bejo Zaden | brassica oleracea plants with a resistance to mycosphaerella brassicicola |
| EP0984693 | 2000-03-15 | Bejo Zaden | method for improving the forming of flowers of a garlic plant |
| EP0810284 | 1997-12-03 | Bejo Zaden | cytoplasmic male sterile brassica oleracea plant and method for obtaining such plant |
| EP1597965 | 2005-11-23 | Seminis | broccoli type adapted for ease of harvest |
| EP1381266 | 2004-01-21 | Seminis | tomato plants that exhibit resistance to <i>Botrytis cinerea</i> |
| EP1045632 | 2000-10-25 | Seminis | starchless pismus sativum plant with elevated levels of sucrose |
| EP1992221 | 2008-11-19 | Ruiter Seeds | closterovirus-resistant plants |
| EP1838847 | 2007-10-03 | Ruiter Seeds | plant virus designated tomato torrado virus |
| EP1804571 | 2007-07-11 | Ruiter Seeds | pmmov resistant capsicum plants |
| EP1433378 | 2004-06-30 | Nunhems Zaden | resistance to powdery mildew infection and absence of necrosis in cucumber, cucumis sativus |
| EP0701619 | 1996-03-20 | Nunhems Zaden | process for generating male sterile plants |
| EP1973397 | 2008-10-01 | Syngenta | novel cucurbita plants |
| EP2061303 | 2009-05-27 | Syngenta | novel rucola plants with cytoplasmic male sterility (cms) |
| EP1887853 | 2008-02-20 | Syngenta | novel brassica plants |
- ix So far only Germany, France and Switzerland have adapted breeders' exemptions in their patent laws which are similar to EC Regulation No. 2100/94 on Community plant variety rights Art. 15(c).^{ix} German Patent Act §11.2a "The effect of the patent does not extend to (...) the use of biological material for the purpose of breeding, discovering and developing a new plant variety." French Intellectual Property Law L.613-2-2 states the rights "do not extend to acts done for the purpose of breeding, or discovering and developing other plant varieties." These exemptions apply to the development of a plant variety with a PTT, but do not permit unlicensed commercialization of the PTT.
- x Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_1/wipo_grtkf_ic_1_8-annex1.pdf. Hereafter referred to as "the Directive."
- xi The European Court of Justice (ECJ) emphasized this concern relating to harmonization in an action brought by the Commission against Italy with respect to the latter's failure to correctly transpose the Directive.
- xii Further, the ECJ's case law concerning the Directive supports the view that the Directive is not limited to only harmonizing patentability. In a 2001 *Netherlands'* case, the Court said that, "the Directive makes certain clarifications and provides for derogations from patent law as regards to the scope of the protection" (emphasis added).
- xiii The Plantum proposal exceeds any derogation from patent law provided in the directive.
- xiv Constitution of The Netherlands: Article 14: Property
- (1) Expropriation may take place only in the public interest and on prior assurance of full compensation, in accordance with regulations laid down by or pursuant to Act of Parliament. (2) Prior assurance of full compensation shall not be required if in an emergency immediate expropriation is called for. (3) In the cases laid down by or pursuant to Act of Parliament there shall be a right to full or partial compensation if in the public interest the competent authority destroys property or renders it unusable or restricts the exercise of the owner's rights to it.
- xv Rabobank Int'l Report; Venkatraman (2002), available under www.blonnet.com/bline/2002/03/25/stories/2002032500240700.htm.