11 Plants and intellectual property rights in the US, Japan, and Europe

Muriel Lightbourne(*)

On June 29, 2004, the international treaty on plant genetic resources for food and agriculture of the United Nations Food and Agriculture Organization (FAO) entered into force. Thus there is an urgent need to find ways to conciliate its implementation together with that of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) and the UPOV Convention for the protection of plant varieties (UPOV).

Rights protecting plant varieties were not provided for by the Paris Convention for the protection of industrial property. On the one hand, the UPOV Convention was later specifically designed, in 1961, to protect such subject matter, and subsequently modified several times. The adoption of this convention aimed at allowing the breeder (who could be a farmer) to forbid the marketing of his plant varieties without his authorization. This protection was initially covering the seeds obtained by applying methods of selection of specified autogame plants, i.e. those whose flowers are fertilized by their own pollen (coleseed, wheat, barley...). The 1991 version of this convention has broadened the rights conferred to breeders, applies to all plant genera and species and does no longer exclude double protection of plants by plant breeders' rights and patents.

On the other hand, Article 27 (3) of the TRIPs Agreement states that "Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof (…)"

In this context, it seems necessary to understand and compare the reach of breeders' rights and of patents in the agricultural field in the United States of America, Japan, and Europe, and to assess the "freedom-to-operate" in future breeding programmes. These rights will be compared as to 1) coverage, and 2) conditions of exercise of rights.

Moreover, for some biotechnological inventions in the field of agriculture, like for other applications of biotechnologies, patent pools may be relevant. The treatment of patent pools under American, Japanese and European antitrust regimes thus has to be rapidly addressed.

I Breeders' rights in the US, Japan and Europe

1 Coverage of breeders' rights in the US, Japan and Europe

(1) In the US

In the U.S., whereas until 1924, farmers were receiving seeds from the Government(*1), a specific regime of property rights had been drafted in 1930 for asexually reproducing plants, excluding tuber-propagated plants, and, later, another specific regime for sexually reproducing plants in 1970. In 1994, the PVPA was modified in order to comply with the 1991 version of the UPOV Convention. Thus, tuber-propagated plants and F1-hybrids (hybrids of first generation) were added to the list of eligible plants.

(i) Criteria for protection

Pursuant to the UPOV Convention, the cultivar (i.e. "cultivated variety") must be new, uniform, stable and distinct from other cultivars. To be considered new, a plant variety must not have been sold or disposed of in the United States for more than one year prior to the filing of the application, or for more than four years in a foreign country (six years in the case of trees and vines).

The US PVP Office does not carry out trials to ascertain that the cultivar fulfils the requirements for protection. The applicant must thus identify the cultivar most similar to the one applied for, and then contrast the two cultivars as to their genetic backgrounds and morphologies.

(ii) Protection of plant variety denominations

The applicant must propose a denomination for the plant variety in the application file; such denomination has to be cleared by the relevant authorities. In the case of vegetables and crops of interest for agriculture, which may be governed by the Federal Seed Act, this authority is the Seed Regulatory and Testing Branch, located in

(*) Research Scholar, Queen Mary Intellectual Property Research Institute, University of London

(*1) In 1897 (high point of this policy), over 20 million packages of seeds were distributed to farmers. See *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International Inc.* decision, II-A paragraph 12. Available at http://supct.law.cornell.edu/supct/html/99-1996.ZS.html

Beltsville, Maryland.

For ornamental plants, not covered by the Federal Seed Act, the SRTB does not maintain any names database. Thus, applicants are only advised to follow the requirements of the Federal Seed Act. The American Seed Trade Association also proposes some guidelines on naming and may act as a clearing agency, when the cultivar is not designated as a certified seed(*2).

(iii) Rights conferred/restricted acts

The plant certificate holder may exclude, for 20 years (25 for trees and vines) from the date of issuance, others from selling, offering for sale, marketing, conditioning or stocking the cultivar, or reproducing, importing or exporting it, or using it to obtain a hybrid. Anyone actively inducing another to perform these acts would also be held liable for infringement. Essentially derived cultivars and indistinct cultivars are covered as well. The PVP certificate also covers harvested materials obtained through the unauthorised use of propagating material of a protected variety, unless the owner of the variety has had a reasonable opportunity to exercise the rights provided under this Act with respect to the propagating material(*3). This so-called "cascading principle" has been introduced by the 1991 version of the UPOV Convention.

(2) In Japan

A law regarding seeds and seedlings, protecting 467 plant varieties(*4), was passed in 1978. The 1978 law was modified in October 1998, so as to be in compliance with the 1991 version of the UPOV Convention. It is now named the Seeds and Seedlings Law no 83 of May 29, 1998.

(i) Species covered

The new law protects all plant genera and species, for a 20-year period – 25 years for trees (as compared with the previous 15-year one – 18 years for trees). The term of "variety" is defined under Sec. 2 (2) of the law, and means "a plant grouping which can be distinguished from any other plant grouping by all or parts of important characteristics and which can be propagated while maintaining the entire characteristics". There is no specific mention in this law of the UPOV notion of "taxon of the lowest known rank". Sec. 3 enumerates the conditions for registration of plant varieties. These are the conditions set forth by the UPOV Convention.

(ii) Protection of plant variety denominations

In Japan, during the examination of an application, a denomination can be modified pursuant to Section 12 of the Law; after registration, Section 41 applies. Section 41 addresses the issue of the necessary coordination between plant variety denominations and trade marks. Accordingly, trade marks are usually registered within 6 months in Japan, whereas it generally requires three years for plant varieties. Thus, during the formality examination, the Ministry of Agriculture, Forestry and Fisheries (hereafter "MAFF") consults the Japanese Patent Office ("JPO") about possible prior application or registration of trade marks for denominations under consideration.

(iii) Rights conferred/restricted acts

The Seeds and Seedlings Law reflects the extension of the coverage of breeders' rights introduced by the 1991 version of UPOV, as well as the "cascading principle". Thus, breeder's rights now consist not only of the production, the sale or offering for sale of the propagating material of the variety, as was the case under UPOV 1978 – still applicable in member countries that have not joined the latest version - but also of the conditioning for the purpose of propagation of said material, its stocking for any of the purposes aforementioned, its importing or exporting. Consequently, plant breeders' rights cover acts of re-import into Japan of fruit produced from protected harvested material.

Apart from the registered variety itself, breeders' rights also cover (pursuant to Sec. 20):

- Varieties which are not distinguishable from the registered variety as to their characteristics;
- Varieties which are bred by changing some characteristics of the registered variety while retaining the essential characteristics of it by selection of a variation, backcrossing, transformation by genetic engineering or other methods and which are clearly distinguishable from the said registered variety as to the characteristics,
- Varieties whose production requires the repeated use of the registered variety.

(*2) For more details, see J. Waltrip *Nomenclature in the North American Seed-Trade*, and Janice M. Strachan *Plant Variety Protection in the USA*, in *Taxonomy of Cultivated Plants – Proceedings of the Meeting Held in Edinburgh, Scotland, 20-26 July 1998*, Edited by Susyn Andrews, Alan Leslie and Crinan Alexander, Published by the Royal Botanic Gardens, Kew, 1999, pp. 53-56 and pp. 67-72.

(*3) 7 U.S.C. 2541 (c)(4).

(*4) Figure quoted by Judge Tomoyuki Tobisawa in *Japan's New Plant Variety Protection System*, in CASRIP Newsletter – Spring/Summer 1998, Volume 5, Issue 2.

(3) In Europe

(i) Criteria for protection

The situation in Europe is characterised by the coexistence of national laws and regulations on the one hand, and of a community regime of protection of plant breeders' rights on the other hand. The Council Regulation EC 2100/94 implements the 1991 version of the UPOV Convention and is administered by the CPV Office, located in Angers, France.

Community plant variety rights (hereafter "CPVRs") have a uniform effect over the Community territory, once granted, but also when they are transferred or cancelled. It is not possible to hold simultaneously CPVRs and national plant variety rights or patents for the same variety. In situations where a national right pre-existed, such right is suspended until the term of the CPVR.

Varieties of all botanical genera and species are entitled to protection. A plant grouping is defined as consisting of entire plants or parts of plants as far as such parts are capable of producing entire plants. The criteria of protection (DUS and novelty tests) are laid down by Art. 5 and 6 of Regulation 2100/94 and correspond to those defined by the UPOV convention.

After issuance, the duration of a CPVR is 25 years (30 years for vines and trees).

(ii) Protection of denominations

Art. 63 of the Regulation 2100/94 sets out detailed rules in this respect. The use within the territory of the Community of the proposed denomination must not be precluded by the prior right of a third party, confusing or misleading as to the characteristics, value or identity of the plant variety, or as to the identity of the breeder, or contrary to public policy in one Member State. Art. 66 indicates how to proceed to the amendment of the plant variety denomination, which may be made *ex officio* by the CPVO, after giving the right holder an opportunity to make a proposal of amendment.

(iii) Rights conferred/restricted acts

These are detailed in Art. 13 of the EC Regulation. They are tantamount to those protected in Japan by the Seeds and Seedlings Law, and by UPOV 1991, in terms of restricted activities, and of definition of the ambit of the protection granted (varieties which are not distinct from the protected variety, essentially derived varieties and hybrids). The originality of the EC Regulation relates rather to the exercise of rights.

2 Exercise of breeders' rights in the US, Japan and Europe

(1) In the US

(i) Assignments and licences

Assignments shall be made and exclusive licences, granted, by an instrument in writing. Additionally, assignments and licences shall be void as against any subsequent purchaser or mortgagee unless it "is filed for recording in the Plant Variety Protection Office within one month from its date or at least one month prior to the date of such subsequent purchase or mortgage."(*5)

A breeder who releases seed or other reproducible or tuber propagable plant material for testing only, with notice thereof, retains ownership with respect to such plant material.(*6)

(ii) Limitations of breeders' rights

Acts done privately and for non-commercial purposes are exempted. Researchers may use and reproduce the protected variety in a breeding programme, and farmers may save seeds of the protected variety for use on their own farm. Moreover, a "bona fide sale for other than reproductive purposes, made in channels usual for such other purposes, of seeds produced on a farm either from seed obtained by authority of the owner for seeding purposes or from seed produced by descent on such farm from seed obtained by authority of the owner for seeding purposes shall not constitute an infringement." (*7)

Any of the restricted acts may be performed, even where a protected variety is multiplied other than sexually, if such acts are performed in pursuance of a valid United States plant patent.

A person who has developed and produced a variety more than one year prior to the effective filing date of an application by another person for a certificate on the same plant variety is entitled to reproduce or sell this variety ("grandfather clause") (*8).

Finally, any person may, within five years after the issuance of a certificate of plant variety protection, ask for the reexamination of such plant certificate(*9).

(*5) 7. U.S.C. 2531 (d).
(*6) 7 U.S.C. 2532.
(*7) 7 U.S.C. 2543.
(*8) 7 U.S.C. 2542.
(*9) 7 U.S.C. 2501.

(2) In Japan

(i) Limitations of breeders' rights

In order to assess the "freedom-to-operate" in breeding programmes, it is necessary to focus on limitations to breeders' rights. These are described in Sec. 21 and consist of:

- The exploitation for the purposes of experiment and research including breeding a new variety,
- The production of the seeds and seedlings of the protected variety by the rightholder of a patent for the process of breeding the registered variety,
- The right to use the product of harvest on their own holdings ("farmers' privilege"), unless there is a contractual waiver of such right.

The Seeds and Seedlings Law (sec. 28) also provides for a non-exclusive right where:

- A registered variety has not been adequately (emphasis added) exploited continuously during a period of 2 years or more in Japan, or
- There is a special public interest in the exploitation of a registered variety.

In case no agreement can be found with the breeder or holder of an exclusive exploitation right, arbitration by the Ministry of Agriculture, Forestry and Fisheries can take place.

(ii) Other limitation

Sec. 35 of the Seeds and Seedlings Law provides for a presumption of negligence, which can be rebutted. In instances of cross-pollinating, if such a rebuttal is admitted, infringement may be found.

(3) In Europe

Art. 13.8 of the EC Regulation 2100/94 posits a general caveat concerning the rights conferred by CPVRs. Without prejudice to farmers' privilege and cross-licensing arrangements, the exercise of CPVRs shall not be contrary to public order, or to the protection of health and life of humans, animals or plants, or of the environment, or of industrial or commercial property, or to the safeguarding of competition and agriculture production.

(i) Limitations of breeders' rights

These are similar to those existing in Japan and defined by the UPOV Convention.

(ii) Farmers' privilege

For the purpose of safeguarding agricultural production, farmers are authorised to use for propagating purposes, on their own holding, the product of the harvest which they have obtained by planting, on their own holding, propagating material of a variety other than an hybrid or synthetic variety, which is protected by a CPVR. However, this faculty applies only in relation to a set of 22 varieties, listed under Art. 14 of the EC Regulation. As a counterpart to this right, farmers shall pay breeders an "equitable remuneration", pursuant to the Commission Regulation EC 1768/95 of 24 July 1995(*10). This obligation does not apply to small farmers.

(iii) Exhaustion of rights

Art. 16 of the EC Regulation is an intricate provision, as can be seen hereunder:

" The Community plant variety right shall not extend to acts concerning any material of the protected variety, or of [a hybrid or a non-distinct or essentially derived] variety, which has been disposed of to others by the holder or with his consent, or any material derived from the said material."

However, there shall be no exhaustion of rights where the protected variety is subject to further propagation, unless such propagation was intended when the material was disposed of. The second exception to the general rule of exhaustion concerns exports of constituents of a protected plant variety into third countries that do not protect varieties of the plant genus or species to which the protected variety belongs, unless such exports are intended for final consumption purposes.

Ⅱ Patent protection for plants in the US, Japan and Europe

1 Patentable plant-related inventions in the US, Japan and Europe

(1) In the US

(i) Plant patents

The Plant Patent Act, which can be found under Title 35 of the United States Code, and is administered by the US Patent and Trademark Office, refers to the general requirements of patentability - in particular non-obviousness – more stringent than those of the UPOV Convention.

Similarly, naming conditions are more specific: the name of the claimed plant must fall within the International Code of Nomenclature

(*10) OJ L173, 25/07/1995, pp. 14-21.

for cultivated Plants, 1980(*11).

As to rights conferred, the Plant Patent Amendments Act of 1998 makes it clear that title 35 U.S.C. protects the owner of a plant patent against the unauthorised sale of plant parts taken from plants illegally reproduced. Thus, "the grant shall include the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States." (*12) These rights are granted for a period of twenty years from filing (and not from issuance, as in the case of plant variety certificates). Mutants of a protected plant are not covered by the PPA granted on this plant.

(ii) Utility patents

The availability of utility patents for plant-related inventions was not obvious, until the USPTO Board of Appeals' decision *in re Hibberd* in 1985(*13). This decision had to be confirmed by the Supreme Court, which was achieved in the *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International Inc.* decision, rendered December 10, 2001. The ruling of this latter decision, adopted with two Justices dissenting, is based on the 1980 *Chakrabarty* decision, according to which "the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions". However, following the dissenting judges, in *Diamond v. Chakrabarty* the Court considered whether the language of 35 U.S.C. section 101, "manufacture or composition of matter", included such living things as bacteria; it was not concerned with the "general coverage for matters to which the special plant statutes do refer (namely, plants)" (*14). The Court recalls that it has in the past given effect to two overlapping statutes, so long as each reaches some distinct cases, and that both the 1930 Plant Patent Act (PPA) and the 1970 Plant Variety Protection Act (PVPA) contain no statement of exclusivity. While section 101 "is a dynamic provision designed to encompass new and unforeseen inventions", "[p]lant patents under the PPA thus have very limited coverage and less stringent requirements than section 101 utility patents"(*15).

(2) In Japan

In 1975, the Japanese patent law no 121 of April 13, 1959, was amended in order to allow chemical compounds and microorganisms to be protected as such. This amendment was followed by a dramatic rise of the R&D investments in the pharmaceutical and agrochemical fields(*16). It was later specified that plants also might be protected by patents.

Revised "Examination Guidelines for Patent and Utility Model" were released on Dec. 28, 2000. Pursuant to these Guidelines, undifferentiated plant cells and plant tissue cultures are treated as microorganisms. Thus, Sec. 27 bis and ter of the Regulation under the Patent Law may apply: they consist in the deposit of a microorganism when it is impossible to describe it, so as to fulfill the enablement requirement; and in certain conditions of access to the deposit for the purpose of tests or experiments.

As to plants *per se*, the Guidelines give some examples where patent protection cannot be secured. In particular, a mere combination of the characteristics of publicly known plants within the species to which the plant belongs (plants obtained by mere crossing) lacks inventive step.

So far, the only decision – as far as this author knows - adopted by the Supreme Court of Japan concerning plant protection is dated 29 February 2000(*17). This decision clarified that the "possibility of repetition in the process of breeding in an invention for a 'method of breeding and multiplying new breed of a plant' (…) is sufficient, if people in the same business are able to reproduce the plant in a scientific way, and do not have to have a high probability of

(*11) The International Code of Nomenclature for Cultivated Plants was first adopted in 1953 and last revised in 1995 (6th edition), and is subordinate to the International Code of Botanical Nomenclature. The rule is that the first validly published name for a particular plant is the one designating this plant. For details, see Chris Brickell and Piers Trehane *The Royal Horticultural Society Advisory Panel on Nomenclature and Taxonomy* in *The New Plantsman* 4(2): 115-119, 1997, available at http://www.rhs.org.uk/research/APONAT1.asp, visited January 7, 2005

(*12) 35 U.S.C. 163.

(*13) For an analysis of the decision, see The American Society of Agronomy *International Property Rights Associated with Plants* (1989). The claims were concerned with the isolation and manipulation of a particular corn mutant derived from cultured tissue of a particular hybrid corn line that possessed the advantages of regenerability and heritability, and directed to "mutant monocot seed" including seed of a "cereal crop" (later restricted to maize).

(*14) *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International Inc.* Dissenting opinion, I – paragraph 5. Available at http://supct.law.cornell.edu/supct/html/99-1996.ZS.html

(*15) Ibid. Decision, II – A, paragraphs 5 and 9.

(*16) Cf. Hiroshi IWATA in *AIPPI Journal* March 1994, p. 56.

(*17) Case no 1998 (Gyo-tsu) 19. Japanese Supreme Court decisions can be retrieved from http://courtdomino2.courts.go.jp

reproduction".

(3) In Europe

Until recently, the situation within Europe was quite murky. Since the entry into force of the European Patent Convention (EPC) in 1978, it was generally admitted that patents could not cover plant varieties, pursuant to Art. 53(b) of this Convention(*18). The latter is the reproduction of Art. 2(2) of the Strasburg Convention, adopted in 1963 but whose wording, at least regarding the aforementioned provision, was already quasi in its final version as of December 1961(*19). Whereas the Strasburg Convention left the option open, the Munich Convention (EPC) precluded the possibility of patent protection for plant varieties. The rationale for this choice was the adoption of the UPOV Convention in 1961, which prohibited double protection for a given variety. However, the UPOV Convention did not exclude plant varieties of the scope of patent protection in general. Nevertheless, as plant breeders' rights were not available in all EPC member States and the principle of uniform patent protection within the EPC territory had to be respected, it was considered simpler, for housekeeping reasons, to adopt such a ban when implementing both the UPOV and the Strasburg Conventions(*20).

The line could no longer be drawn so easily after the European Community adopted in an E.C. Regulation the contents of the 1991 version of the UPOV Convention, which allows the concurrent protection of a plant variety by breeders' rights and by patent.

The *Novartis* decision of December 20, 1999 of the Enlarged Board of Appeal of the European Patent Office partly clarifies the issue. The Enlarged Board first reminds that "the term plant variety in Article 53(b) EPC had the same meaning as in the UPOV Convention and the excluding provision should only apply if such varieties were claimed *per se*" (*21) (in a product patent). Moreover, according to established case law, "the protection conferred by a process patent is extended to the products obtained directly by the process, even if the products are not patentable *per se*". Thus, like in the U.S., the patent protection and plant breeders' rights may overlap(*22). Effectively, the ruling of the Enlarged Board is that a "claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC, even though it may embrace plant varieties". The Enlarged Board specifies that the exclusion applies irrespective of the way in which the plant varieties are produced and that thus, "plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability".

This decision, which overrules the previous position held in the *Plant Genetic System* case (1995), rapidly refers to two recitals of the E.C. Directive 98/44 on the protection of inventions relating to biotechnology(*23) to justify the "more than one variety approach". It insists as well as on Article 12 of same Directive, which takes into account the interests of the breeder who cannot obtain or exploit a plant variety right without infringing a prior patent, and vice-versa (cf. the situation where an "essentially derived variety" is obtained). In such a situation, the breeder or the patent holder is entitled to a compulsory licence for non-exclusive use, subject to a royalty. The relations between the two types of title are thus more organised in the European system than in the U.S. It is also clear from the EPC and the European case law that patents cannot be granted for essentially biological process, although this seems to be the practice of the USPTO.

(*18) "European patents shall not be granted in respect of: (…);
(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof."

(*19) The December 1961 version of the Strasburg Convention on the unification of certain points of substantive law on patents for invention reads as follows:
"Nevertheless, the Contracting States shall not be bound to provide for the grant of patents in respect of plant or animal varieties or of essentially biological processes for the production of plants or animals"; see S.A. Bent, R.L. Schwaab, D.G. Gonlin and D.D. Jeffery *Intellectual Property Rights in Biotechnology Worldwide* – M. Stockton Press 1987.

(*20) See paragraph 3.5 of the *Transgenic Plant/Novartis II* decision of the EPO Enlarged Board of Appeal of December 20, 1999.

(*21) See decision, respectively paragraph VIII of Summary of facts and submissions and paragraph 4 of Reasons for the decision. Available in UPOV gazette 87/200, pp. 29-38.

(*22) Note that the protection conferred by the UPOV Convention covers the seeds ("propagating material"), just like patents do, but not the genes or combination of genes, neither the process.

(*23) The EPC is an international convention and does not pertain to the E.C. legal system; however, the EPO takes into account the E.C. Directive, as many of its member States have to implement it. In its decision of 16 June 1999, the Administrative Council of the EPO inserted a new Chapter VI entitled "Biotechnological inventions" in Part II of the EPC Implementing Regulations and amended the wording of Rule 28(6) EPC – see Notice dated July 1, 1999 in OJ EPO no. 8-9 of August-September 1999, pp. 545-587.

2 Articulation between plant breeders' rights and patents

(1) In the US

Any of the acts restricted by the PVPA may be performed, even where a protected variety is multiplied other than sexually, if such acts are performed in pursuance of a valid United States plant patent. Thus, a plant patent owner will not infringe a plant variety certificate, as long as, in compliance with the plant patent system itself, such patent owner reproduces the plant variety asexually. A plant variety may be protected by a plant variety certificate, and covered as well by a plant patent for a cloning method or a mutant of this variety. This necessary measure of coordination between the PPA and the PVPA thus limits the protection granted through plant variety certificates, in order to avoid the stifling of further innovation.

(2) In Japan

In this respect, the Seeds and Seedlings Law includes an interesting provision. Effectively, Sec. 21 (1) of the Seeds and Seedlings Law states that:

> "The effects of a breeder's right shall not extend to the following acts:
>
> (…) (ii) Production of seeds and seedlings of the registered variety, by a person who has a patent for the process of breeding the registered variety (including a variety which is not clearly distinguishable from the registered variety…)"

Thus, breeders cannot oppose the effects of the scope of protection of process patents, where seeds and seedlings of a registered variety (or of a variety not distinguishable from the protected one) are obtained by a patented method. Effectively, under patent regimes, products obtained through the patented method are covered by the process patent.

(3) In Europe

In Europe, the Directive 98/44/EC on the legal protection of biotechnological inventions contemplates such a situation, and Article 12 designed a cross-licensing scheme between patents and plant breeders' rights. The conditions set forth for such licenses are the following ones:

- They must be compulsory licenses,
- For a non-exclusive use,
- Giving rise to appropriate royalties.

This provision was inspired by the conditions listed in Art. 31 of the TRIPs (which is concerned only with compulsory licenses on patents). In particular, the applicant must give evidence of his/her unsuccessful attempt to obtain a contractual license; and the plant variety or the invention concerned must represent a significant technical progress of considerable economic interest.

The Regulation 2100/94 on Community plant variety rights had to be amended accordingly, which was achieved by the Council Regulation (EC) 873/2004 that modifies Art. 29 of Regulation 2100/94. The new Regulation specifies the conditions of grant of cross-licenses.

Conclusion

The application to breeding programmes of the research exemption under the Japanese Patent Law calls for an interpretation by the Courts. The solution given to a case where a breeder and a patent-holder need to resort to cross-licenses in order to work their respective inventions would be of the utmost interest.

Within Europe, the manner in which dependence situations are going to be solved through the scheme set out by Art. 12 of the Directive 98/44 and Art. 29 of Regulation 2100/94 remains to be seen. Likewise, the interpretation by national courts of research exemption provisions in national patent laws is of special interest, in particular with respect to market harmonisation.

More significantly, there is a need for a broader research exemption in the United States, statutorily and at common law. Additionally, the relationship between patents and plant breeders' rights in situations of dependence have to be organised.