

FOOD SECURITY

Patenting of plant varieties and plant breeding methods

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Journal of Experimental Botany, Vol. 63, No. 3, pp. 1069–1074, 2012

doi:10.1093/jxb/err368

Abstract

This article considers the relationship between patenting and plant variety rights protection, through a detailed analysis of the recent determination by the Extended Board of Appeal of the European Patent Office that methods for breeding broccoli and tomatoes were not patentable. It concludes that the right to patent agricultural innovations is increasingly located within a political context.

Key words: Intellectual Property, Patents, Plant Breeding, Plant Variety Rights Protection.

Plant variety protection

The development of new plant varieties is protectable in most countries as a species of intellectual property right (IPR) derived from the International Convention for the Protection of New Varieties of Plants (UPOV) (see note ¹). Countries which are members of the World Trade Organization (WTO) are obliged by Article 27.3(b) of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) to ‘provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof’. The TRIPS Agreement does not specify which ‘*sui generis* system’ will meet its requirements, but most of the 153 members of the WTO have promulgated domestic legislation based upon the 1991 version of UPOV.

UPOV allows the protection of new varieties of plants which are distinct, uniform, and stable. A variety is considered to be new if it has not been commercialized for more than one year in the country of protection. A variety is distinct if it differs from all other known varieties by one or more important botanical characteristics. A variety is uniform if the plant characteristics are consistent from plant to plant within the variety. A variety is stable if the plant characteristics are genetically fixed and therefore remain the same from generation to generation, or after a cycle of reproduction in the case of hybrid varieties. The 1991 version of UPOV recognizes the right of breeders to use protected varieties to create new varieties. However, this exception is itself restricted to such new varieties as are not ‘essentially derived’ from protected varieties. The drafters added this restriction to prevent second generation breeders from making merely cosmetic changes to existing varieties in order to claim protection for a new variety. From the perspective of farmers, probably the most contentious aspect of the 1991 Act is the limitation of the farmers’ privilege to save seed for propagating the product of the harvest they obtained by planting a protected variety ‘on their own holdings’, ‘within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder’ (see note ²). Earlier versions of UPOV permitted farmers to sell or exchange seeds with other farmers for propagating purposes.

The seed-saving privilege and the permitted development of non-essentially-derived new varieties from protected material were compromises built in to the legislation to take account of public policy concerns. It was appreciated that permitting individuals to privatize food varieties might compromise food security if breeding material was locked up and if farmers were prevented from saving seed for further harvests. However, from the perspective of plant breeders, any derivation of new varieties from their protected varieties, whether essential or non-essential, was inconvenient for them and any seed-saving by farmers deprived them of new sales. Consequently, they looked to patents law, which does not contain these exceptions, to protect their new varieties.

⁽¹⁾ International Convention for the Protection of New Varieties of Plants (official English transl.) (1991), at <http://www.upov.org/eng/convntns/1991/act1991.htm>; Accessed 10 March 2011.

⁽²⁾ International Convention for the Protection of New Varieties of Plants (official English transl.) (1991), at <http://www.upov.org/eng/convntns/1991/act1991.htm>; Accessed 10 March 2011. Article 15(2).

Patenting of plant varieties in the USA

The USA has never excluded biological material, including plant varieties from the scope of patentable subject matter. Plant varieties can be protected in the USA under a system of plant patents, or under a system of utility patents or under the Plant Variety Protection Act (PVPA). The Plant Patent Act (see note ³) makes available patent protection to new varieties of asexually reproduced plants. Under this scheme, a plant variety must be novel and distinct and the invention, discovery or reproduction of the plant variety must not be obvious. One of the disadvantages of the scheme is that only one claim, covering the plant variety, is permitted in each application. The Federal Circuit Court of Appeal resolved any potential conflict between patent protection and protection under the Plant Variety Protection Act (PVPA) in its decision in *Pioneer Hi-Bred International Inc. v. J.E.M. Ag Supply Inc* (see note ⁴). Pioneer's patents covered the manufacture, use, sale, and offer for sale of the company's inbred and hybrid corn seed products as well as certificates of protection under the Plant Variety Protection Act for the same seed-produced varieties of corn. The defendants argued that the enactment of the Plant Variety Protection Act had removed seed-produced plants from the realm of patentable subject matter the Patents Act. The Federal Circuit rejected this argument noting that the Supreme Court held that 'when two statutes are capable of co-existence, it is the duty of the courts ... to regard each as effective'.

This was illustrated by *Monsanto Co. v. McFarling* (see note ⁵) which concerned Monsanto's patent for glyphosate-tolerant plants, the genetically modified seeds for such plants, the specific modified genes, and the method of producing the genetically modified plants (see note ⁶). Monsanto required that sellers of the patented seeds obtained from purchasers a 'Technology Agreement', in which they agreed that the seeds were to be used 'for planting a commercial crop only in a single season' that the purchaser would not 'save any crop produced from this seed for replanting, or supply saved seeds to anyone for replanting'. Mr McFarling, a farmer in Mississippi, purchased Roundup Ready soybean seed in 1997 and again in 1998; he signed the Technology Agreement. He saved 1500 bushels of the patented soybeans from his harvest during one season and, instead of selling these soybeans as crop, he planted them as seed in the next season. He repeated this activity in the following growing season. This saved seed retained the genetic modifications of the Roundup Ready seed. Mr McFarling did not dispute that he violated the terms of the Technology Agreement but claimed that the contractual prohibition against using the patented seed to produce new seed for planting, when he produced only enough new seed for his own use the following season,

violated the seed saving provision of the PVPA. The Court declined to limit the patent law by reference to the PVPA and Mr McFarling was found to have infringed Monsanto's patent.

Patenting of plant varieties in Europe

The situation in Europe is complicated by the fact that the European Patent Convention (EPC) takes account of UPOV and, in Article 53(b), specifically excludes the patenting of 'plant or animal varieties or essentially biological processes for the production of plants or animals', explaining that 'this provision shall not apply to microbiological processes or the products thereof'. Rule 23b(5) of the EPC explains that a process for the production of plants and animals is essentially biological 'if it consists entirely of natural phenomena such as crossing or selection'. This language is replicated in the EU Biotechnology Directive which in Article 4.1 excludes from patentability: (a) plant and animal varieties; and (b) essentially biological processes for the production of plants or animals. Article 2.2 states that a process for the production of plants or animals is essentially biological 'if it consists entirely of natural phenomena such as crossing or selection'.

The Biotechnology Directive leaves the door open to the patenting of plant varieties because Article 4.2 provides that, 'Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety'. This qualification was addressed by the Technical Board of Appeal of the European Patent Office (EPO) in *Novartis/Transgenic Plant* (see note ⁷). The patent application in that case concerned a patent containing claims to transgenic plants comprising in their genomes specific foreign genes, the expression of which resulted in the production of antipathologically active substances, and to methods of preparing such plants. The EPO had denied registration, supported by the Technical Board of Appeal, on the ground that Article 53(b) denied the patentability of an invention which could embrace plant varieties. The EPO's Enlarged Board of Appeal (EBA) noted that the definitions of plant variety in the UPOV Convention and the EC Regulation on Community Plant Variety Rights refer to 'the entire constitution of a plant or a set of genetic information', whereas a plant defined by a single recombinant DNA sequence 'is not an individual plant grouping to which an entire constitution can be attributed'. It observed that the claimed transgenic plants in the application before it were defined by certain characteristics which allowed the plants to inhibit the growth of plant pathogens. No claim was made for anything resembling a plant variety. The Enlarged Board of Appeal noted that, in the case of plant variety rights, an applicant had to develop a plant group, fulfilling in particular the requirements of homogeneity and stability,

⁽³⁾ 35 U.S.C. §§ 161–164 (1994).

⁽⁴⁾ 200 F.3d 1374 (Fed. Cir. 2000), cert. granted, 148 L. Ed. 2d 954 (2001)

⁽⁵⁾ 302 F.3d 1291 (Fed. Cir. 2002).

⁽⁶⁾ US Patents Nos. 5,633,435 and 5,352,-605.

⁽⁷⁾ [2000] O.J. EPO 511.

whereas in the case of a typical genetic engineering invention, a tool was provided whereby a desired property could be bestowed on plants by inserting a gene into the genome of a specific plant. It observed that the development of specific varieties was not necessarily the objective of inventors involved in genetic engineering.

Implications of patenting for plant variety rights protection

Given the interrelationship between patents and plant variety protection there is the possibility that a plant breeder in developing a new variety might infringe a patent. To deal with this situation, the EU Directive on Protection of Biotechnological Inventions in Article 12 provides for compulsory cross-licensing in situations where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent. In such instances, the breeder may apply for a compulsory license for non-exclusive use of the patent, which will be granted 'subject to payment of an appropriate royalty'. Reciprocally, a compulsory licence also applies in situations where a patent holder cannot exploit an invention without infringing a plant variety right.

On 6 May 2009, Plantum NL (2011), the Dutch association for breeding, tissue culture, production, and trade of seeds and young plants, announced its position on the relationship between patents and plant breeders' rights. It stated that:

- (i) Biological material protected by patent rights should be freely available for the development of new varieties.
- (ii) The use and exploitation of these new varieties should be free, in line with the 'breeders' exemption' of the UPOV Convention.
- (iii) The aforementioned free availability, use and exploitation should not be allowed to be obstructed in any way, either directly or indirectly, by patent rights.

It notes that contemporary plant breeding involves the use of various high-tech procedures which serve to improve and/or speed up the selection process, such as EMS mutagenesis, gene mapping, embryo rescue, double haploidization, and selection based on DNA markers. Since patent laws, in general, do not have a provision which can be compared with the breeders' exception, varieties containing patented traits or which have been developed using a patented process are not freely available for further breeding. Plantum NL notes the significant increase in the number of plant-related patent applications (see note ⁸) and that, although France and Germany have included an exemption for plant breeding in their national patent law, since 2004, a number of companies with strong patent portfolios have been advocating that this position should be changed to disallow further breeding of progeny containing a patented trait. It claims that this

agitation 'has resulted in some companies explicitly requesting that their competitors abandon plant breeding programmes which allegedly infringe their patent applications with the immediate effect of dramatically hampering innovation and posing a threat to those companies which are trying to develop competitive varieties'. Plantum NL concludes that 'these developments pose a threat to the tried and tested system of open innovation within the plant breeding sector'.

Patenting of plant breeding methods

The exclusion by the European patent legislation of 'essentially biological processes for the production of plants or animals' defined in Article 2.2 of the Biotechnology Directive as consisting 'entirely of natural phenomena such as crossing or selection', would have been thought to deny patent protection to plant breeding methods, but this was tested recently by the EPO Enlarged Board of Appeal in two determinations. One concerned whether a process involving crossing and selection of broccoli (see note ⁹) could be patentable. Another referral concerned a similar type of invention relating to crossing and selection of tomatoes (see note ¹⁰).

The broccoli patent application was filed by Plant Bioscience Ltd. (Norwich/UK) for a 'method for selective increase of the anticarcinogenic glucosinolates in brassica species' (see note ¹¹). The tomato patent application was filed by the Israeli Ministry of Agriculture for 'method for breeding tomatoes having reduced water content and product of the method' (see note ¹²). Both of the patent applications were opposed by interested parties. These oppositions were heard by the EPO's Technical Board of Appeal which referred to a number of questions to be determined by the EBA. In relation to the broccoli patent the questions were:

- (i) Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?
- (ii) If question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

⁽⁹⁾ Case G2/07.

⁽¹⁰⁾ Case G1/08.

⁽¹¹⁾ Patent specification EP 1069819, published 24.7.2002.

⁽¹²⁾ Patent specification EP 1211926 published, 26.11.2003.

⁽⁸⁾ 4500, most of which have been filed in the past 10 years.

The questions raised in respect of the tomatoes referral were:

(1) Does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?

(ii) If question 1 is answered in the negative, does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?

(iii) If question 2 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

The EBA answered the questions as follows:

(i) A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being ‘essentially biological’ within the meaning of Article 53(b) EPC.

(ii) Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.

(iii) If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.

(iv) In the context of examining whether such a process is excluded from patentability as being ‘essentially biological’ within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.

The EBA identified from the jurisprudence the following elements which had been enumerated as relevant to determining whether a process is not essentially biological:

- (i) The totality of human intervention and its impact on the result achieved is to be determined.
- (ii) This has to be judged on the basis of the essence of the invention.
- (iii) The impact must be decisive.
- (iv) The contribution must go beyond a trivial level.
- (v) The totality and the sequence of the specified operations must neither occur in nature nor correspond to the classical breeders’ processes.
- (vi) The required fundamental alteration of the character of a known process for the production of plants may lie either in the features of the process, i.e. in its constituent parts, or in the special sequence of the process steps, if a multistep process is claimed (see note ¹³).

It had been argued in the proceedings that crossing and selection should be understood to mean only crossing and selection as they take place in nature. In particular, the term selection did not address the selection made by man in a breeding process but only the selection that takes place in nature and is not controllable by man, and that determines which plants survive in nature. The EBA ruled that applying the principles of treaty interpretation the meaning of a term of a treaty could not be established in a purely semantic manner but its interpretation must be made in good faith, in accordance with the ordinary meaning to be given to the terms of the treaty in their context (see note ¹⁴).¹ Thus it observed that a definition which completely disregarded the fact that the context of the terms crossing and selection in the provisions of the EPC is given by the processes for the production of plants, the terms ‘crossing’ and ‘selection’ refer to acts performed by the breeder. These are characterized by the fact that the breeder intervenes in the processes in order to achieve a desired result. Hence, in that context, crossing and selection are not natural phenomena but are method steps which generally involve human intervention.

The technical requirement for patentable inventions

The Broccoli and Tomato determinations of the EBA, raise the underlying question of what botanical innovations constitute a patentable invention for the purposes of patent law. The answer to this question will differ according to the national patent law which is in force.

The USA is considered to have the most liberal patent law. In 1980, the Supreme Court in *Diamond v Chakrabarty* (see note ¹⁵) had to consider whether a genetically engineered bacterium, capable of breaking down multiple components of crude oil, was patentable. The patent examiner in that case had rejected the application on two

⁽¹³⁾ Eg Case G1/08, at p.35.

⁽¹⁴⁾ Eg Case G1/08, at pp. 38-39.

⁽¹⁵⁾ 447 US 303 (1980).

grounds: (i) that micro-organisms are ‘products of nature’ and (ii) that as living things they were not patentable subject matter under the US patent law. The Supreme Court brushed aside these concerns, famously referring to the objective of Congress that the patent law was to ‘include anything under the sun that is made by man’ as patentable. Accordingly, the Court ruled that the micro-organism qualified as patentable subject matter. However, the Court also noted that the patent claim under consideration ‘was not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity’ (see note ¹⁶). In other words, some human intervention was required to render a biological innovation as patentable.

The European Patent Office focuses upon the necessity for a claimed invention to have a ‘technical’ character. Rule 27 Implementing Regulations to the Convention on the Grant of European Patents defines patentable biotechnological inventions as those which concern:

- (i) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;
- (ii) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;
- (iii) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

This requirement that inventions have a technical character was considered by the EBA in the Broccoli and Tomato cases to be an important matter in its consideration of whether plant breeding methods were patentable. In examining the historical documents which led up to the formulation of the EPC in 1960, the EBA observed that, with the creation of new plant varieties for which a special property right was going to be introduced under the subsequent UPOV Convention in 1960, the legislative architects of the EPC were concerned with excluding from patentability the kind of plant breeding processes which were the conventional methods for the breeding of plant varieties of that time. These conventional methods included, in particular, those based on the sexual crossing of plants deemed suitable for the purpose pursued and on the subsequent selection of the plants having the desired trait(s). These processes were characterized by the fact that the traits of the plants resulting from the crossing were determined by the underlying natural phenomenon of meiosis. This phenomenon determined the genetic make-up of the plants produced, and the breeding result was achieved by the breeder’s selection of plants having the desired trait(s). That these were processes to be excluded also followed from the fact that processes changing the genome of plants by

technical means such as irradiation were cited as examples of patentable technical processes.

The EBA also referred to the explanations given in the memorandum of the Secretariat of the Committee of Experts for agreeing to the replacement of the words ‘purely’ biological by the word ‘essentially’ was deliberate as reflecting the legislative intention that the mere fact of using a technical device in a breeding process should not be sufficient to give the process as such a patentable technical character. The EBA concluded that the provision of a technical step, be it explicit or implicit, in a process which is based on the sexual crossing of plants and on subsequent selection does not cause the claimed invention to escape the exclusion if that technical step only serves to perform the process steps of the breeding process (see note ¹⁷).

Conclusion

The determination of the EBA was that a process for the production of plants which is based on the sexual crossing of whole genomes and on the subsequent selection of plants, in which human intervention, including the provision of a technical means, serves to enable or assist the performance of the process steps, is excluded from patentability as being essentially biological within the meaning of Article 53(b) EPC. Thus the EBA confirmed that classical plant breeding is excluded from patentability. On the other hand, if a process of sexual crossing and selection includes within it an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then that process leaves the realm of the plant breeding and, consequently, is not excluded from patentability. This principle applies only where the additional step is performed within the steps of sexually crossing and selection, independently from the number of repetitions, otherwise the exclusion of sexual crossing and selection processes from patentability could be circumvented simply by adding steps which do not properly pertain to the crossing and selection process, being either upstream steps dealing with the preparation of the plant(s) to be crossed or downstream steps dealing with the further treatment of the plant resulting from the crossing and selection process. The EBA noted that, for the previous or subsequent steps, per se patent protection was available. This will be the case for genetic engineering techniques applied to plants which differ from conventional breeding techniques as they work primarily through the deliberate insertion and/or modification of one or more genes in a plant.

It is important to note that the EBA disallowed the patenting of methods of plant breeding. It has been pointed out that the products of plant breeding remain patentable

⁽¹⁶⁾ 447 US 303 (1980), at p.310.

⁽¹⁷⁾ 447 US 303 (1980), pp. 66–67.

(Then and Tippe, 2011). An analysis of the examination reports for recent patent applications at the EPO indicate that claims in relation to the breeding of plants would have to be deleted, but that the plants themselves [sunflowers (see note ¹⁸) and coreless tomatoes (see note ¹⁹)] were patentable. Because of this, civil society representatives have 'a clear legal prohibition on granting patents on plants and animals, on processes for breeding, relevant biological material and the food derived' (see note ²⁰).

This litigation emphasizes for plant breeders and botanists the political dimension of their activities, which had hitherto been treated as a matter of technical science. The environmentalist NGO, Greenpeace, is cofounder of 'No Patents on Seeds', and has taken the lead in building public awareness of the issue. Similarly, the NGO, ETC Group, has led a campaign over many years opposing the 'patenting of life'. An illustration of the strength of feelings on this issue was the destruction by Greenpeace activists in July 2011 of a GM wheat crop being grown at a government experimental station in Australia (see note ²¹). The attack followed the refusal of a Freedom of Information request for more information about the trials. The GM trials were part of experimentation into the development of drought-resistant crops. Underpinning the opposition to this science is the concern of NGOs that the independence of small independent farmers and breeders is threatened by powerful life sciences corporations.

A 2008 study by the ETC Group identified 55 patent 'families' (see note ²²) (a total of 532 patent documents) that were applied for and/or granted to a number of biotechnology companies on so-called 'climate-ready' genes at patent offices around the world (ETC, 2008). Its 2010 update of this study 'examined patents containing claims concerned with abiotic stress tolerance (ie traits related to environmental stress, such as drought, salinity, heat, cold, chilling, freezing, nutrient levels, high light intensity, ozone, and anaerobic stresses' (ETC, 2010). It noted a dramatic upsurge in the number of patents published (both applications and issued patents) related to 'climate-ready' genetically engineered crops from 30 June 2008 to 30 June 2010, identifying 262 patent families and 1663 patent documents (ETC, 2010, Appendix I). The 2010 report of the ETC contrasted the ownership of 9% patent families by public sector institutions (9% of the total) with the private sector which holds 91% of the total. The 2010 report points out that 'just three companies—DuPont, BASF, Monsanto

—account for two-thirds (173 or 66%) of the total'. This level of market concentration gives cause for concern for those who espouse the positive role of competition, but also a concern about the sort of biotechnological research which is undertaken. For example, to what extent will the dominance of private corporations in biomedical and agricultural research direct that research towards Northern concerns away from Southern food priorities (Alston *et al.*, 1998). It has been estimated that only 1% of the research and development budgets of multinational corporations is spent on crops of interest that would be useful in the developing world (Pingali and Traxler, 2002). Almost entirely neglected by these corporations are the five most important crops of the poorest, arid countries—sorghum, millet, pigeon pea, chickpea, and groundnut (Ziegler, 2008, para.44).

This disputation over the patenting of the products of plant breeding, as well as plant breeding methods themselves, emphasizes the increasingly politicized environment in which experimental botany is occurring. Current research into the influence of climate change upon the development of weeds, insect pests, and crop diseases and the ways in which plants can be engineered to withstand salinity and aridity is increasingly going to be undertaken in a political context. Notes

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⁽¹⁸⁾ EP 1793661 application by the Biogemma company.

⁽¹⁹⁾ EP 1026942, application by Seminis company.

⁽²⁰⁾ <http://www.no-patents-on-seeds.org/en/information/news/european-patent-office-issues-broccoli-decision>, Accessed 14 March 2011.

⁽²¹⁾ <http://www.news.com.au/features/environment/greenpeace-attacks-canberra-gm-wheat-it-says-is-for-secret-human-trials-links-monsanto/story-e6frfp0-1226094379010#ixzz1a2qAoEYI>, Accessed 7 October 2011.

⁽²²⁾ A patent family contains a set of related patent applications and/or issued patents that are published in more than one country or patent office (including national and regional patent jurisdictions). Issued patents and/or applications that belong to the same family have the same inventor and they refer to the same 'invention'.