Genes and Plant Breeding in an IPR-led World

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Abstract
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Media Summary
Intellectual property laws are impacting on plant breeding and upon the genetic modification of plants. This paper traces the history of the impact of intellectual property laws on these areas and concludes with an examination of the impact of these developments upon the international agricultural research environment and the food security debate.

1.Intellectual Property Rights and Agriculture

The first international intellectual property convention was the 1883 Paris Convention for the Protection of Industrial Property. In this instrument agriculture was envisaged as an area of enterprise in respect of which property rights could be secured, thus Article 1(3) of the Convention had declared that

Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers and flour.

Given the state of technology in 1883, the inclusion of these agricultural subjects within the Paris Convention, was in the context of the protection of trade marks and indications of source.

The first inclusion of agricultural innovations in an intellectual property statute was the US Plant Patents Act of 1930, which created a sui generis system of protection for agricultural innovations, confining protection to asexually reproduced plants, because of the view that sexually reproduced varieties lacked stability.[1] The section also excluded tuber-propagated plants principally because of a concern that this would lead to monopolies in basic foodstuffs such as potatoes.[2] Applicants for Plant Patents were required to asexually reproduce the plant in relation to which protection was sought to demonstrate the stability of the characteristics of the plant which were claimed. Section 161 required that new varieties be "distinct". The statute did not define this requirement, although the Senate Committee report accompanying the Act, stated that "in order for a new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties" and that it was not necessary for the new variety to constitute "a variety of a new species".[3]

Legislation, similar to the Plant Patents Act was adopted in Cuba, 1937; South Africa, 1952 and the Republic of Korea, 1973.

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1 See S.B. Williams, 'Intellectual property Aspects of Plant Variety Genetic Engineering: View of an American Lawyer' UPOV, *Genetic Engineering and Plant Breeding*, 1983, 23.

2 Senate Report accompanying S.4025, Report No. 315, 71st Cong., 2d Sess.

3 *Ibid*., cited by J. Rossman, 'The Preparation and Prosecution of Plant Patent Applications' (1935) J. Patent Office Society 632.

2. Plant Variety Rights Protection

2.1 Development of Sui Generis Plant Variety Rights Protection

As with other categories of intellectual property, a key role in the inclusion of agricultural innovations within the international regulatory regime was played by industry associations. The Congrès pomologique de France, held in 1911, had called for special protection for plant varieties. This agitation continued in the 1920s and 30s, culminating in the foundation in Amsterdam on 17 November 1938, of the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL). At its Semmering Congress in June 1956 a resolution of ASSINSEL called for an international conference to promulgate an international system for the protection of plant varieties. On 22 February 1957, the French Government issued invitations to 12 Western European countries[4] to attend a diplomatic conference in Paris Conference from May 7 to 11, 1957 to consider establishing such a system. Participation was limited by the French to those states who were known to have similar concerns to it on this subject. The conclusions of the 1957 Conference were set down in its Final Act, adopted on May 11, 1957. This recognised the legitimacy of breeders' rights and established as the preconditions for protection, that a variety had to be distinct from pre-existing varieties and sufficiently homogenous and stable in its essential characteristics. It defined the rights of the breeder and acknowledged the principle of the independence of protection. At the second session of the Conference, held in Paris from 21 November to 2 December, 1961, an International Convention for the Protection of New Varieties of Plants (UPOV) was adopted. Article 4(1) applied the Convention to "all botanical genera and species", but it was envisaged that the Convention would have a gradual introduction. A list of 13 genera was annexed to the Convention: wheat, barley, oats or rice, maize, potato, peas, beans, Lucerne, red clover, ryegrass, lettuce, apples, roses or carnations. Article 4(3) required each member State on entry into force of the Convention to apply it to at least five genera from this list and within eight years to all the listed genera.

Article 27 of the 1961 Convention provided for its periodic review, with the first revision scheduled for 1972. Within the first 19 years of its life, the UPOV Convention had attracted the accession of only 12 States. A reason which was identified for the reluctance of States to adopt the Convention was the stringency of its provisions, in particular the obligation of states to select either patent or UPOV-style protection for plant varieties. Article 2 of the Convention was amended to permit the accession of countries like the USA, which had laws allowing or the double protection of varieties under patent and sui generis laws. The list of genera, annexed to the 1961 Convention was removed. This list had contained mainly species from temperate climates. Under the new Article 4, member states agreed to apply the Convention to at least five genera or species, rising to 24 genera of species within eight years. Additionally a grace period was introduced, to permit the marketing of varieties 12 months prior to an application for plant variety protection being made.

A further broadening of the UPOV Convention occurred with the 1991 Revision. The 1991 Act requires states to protect at least fifteen plant genera or species upon becoming members of the Act, and to extend protection to all plant varieties within ten years (Article 3(2)). In response to demands from breeders in industrialized counties, the 1991 Act removed the prohibition against dual protection. The 1991 Act recognized the right of breeders to use protected varieties to create new varieties. However, this exception is itself restricted to such new varieties as were not "essentially derived" from protected varieties (Articles 14(5), 15). 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. The concept of essential derivation has proved highly controversial in practice, however. Breeders have been unable to agree on a definition of the minimum genetic distance required for second generation varieties to be treated as not essentially derived from an earlier variety and thus outside of the first breeder's control.[5]

From the perspective of farmers, probably the most contentious aspect of the 1991 Act was the limitation of the farmers' privilege to save seed for propagating "on their own holdings" the product of the harvest which they obtained by planting a protected variety "on their own holdings", "within reasonable limits

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4 Ie Austria, Belgium, Denmark, Finland, Federal republic of Germany, Italy, the Netherlands, Norway, Spain, Sweden, Switzerland and the UK.

5 See L. Helfer, *Legal Study on Intellectual Property Rights in Plant Genetic Resources*. FAO, Rome, 2001. para.1.1.1.4.

and subject to the safeguarding of the legitimate interests of the breeder" (Article 15(2)). Unlike the 1978 Act, the 1991 version of the farmers' privilege does not authorize farmers to sell or exchange seeds with other farmers for propagating purposes. This is criticized as inconsistent with the practices of farmers in many developing nations, where seeds are exchanged for purposes of crop and variety rotation.[6]

A number of developing countries have resisted the adoption of the 1991 Act as the standard for plant variety protection laws. The foreign ministers of Organization for African Unity issued a statement at a January 1999 meeting calling for a moratorium on IPR protection for plant varieties until an Africa-wide system had been developed that granted greater recognition to the cultivation practices of indigenous communities.

2.2 Plant Variety Rights Protection and the TRIPS Agreement 1994

Probably the most notorious requirement of the TRIPS Agreement is that in Article 27.3(b) which requires 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". The provision, when it was introduced in 1994, provided for its own review within four years by the Council for TRIPS. A *Communication* to the WTO from Kenya, on behalf of the African Group, to assist the Preparations for the 1999 Ministerial Conference, suggested that "after the sentence on plant variety protection in Article 27.3(b), a footnote should be inserted stating that any sui generis law for plant variety protection can provide for:

(i) the protection of the innovations of indigenous and local farming communities in developing countries, consistent with the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources;
(ii) the continuation of the traditional farming practices including the right to save, exchange and save seeds, and sell their harvest;
(iii) preventing anti-competitive rights or practices which will threaten food sovereignty of people in developing countries, as is permitted by Article 31 of the TRIPS Agreement."

This African proposal is reflected in part in the Doha Ministerial Declaration of November 2001, which in Clause 19 provided:

19. We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."

2.3 Technical Issues Relating to Patent and Plant Variety Protection Under Article 27.3(b)

Article 27.1 of the TRIPS Agreement provides that, subject to two categories of exception, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". Excluded from patentability, by Art.27.2 is the exploitation of inventions "which is necessary to protect *ordre public* or morality, including to protect human or plant life or health or to avoid serious prejudice to the environment…." Article 27.3 permits the exclusion from patentability of (b) plants and animals, other than microorganisms, and essentially biological processes for the production of plants and animals, other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

A *sui generis* option in the intellectual property context is usually taken to refer to a specially coined IP right outside the traditional categories of IP protection. UPOV has advanced its system as the principal

[6] D. Leskien, and M. Flitner, 'Intellectual Property Rights and Plant Genetic Resources: Options for a sui generis system'. (1997) No 6, *Issues in Genetic Resources*, Rome, IPGRI, 60.

workable example of a *sui generis* plant variety protection system. In order to help countries devise an appropriate *sui generis* system, the International Plant Genetic Resources Institute (IPGRI) came up with a list of key questions that decision makers should take into account[7]. These are as follows:

- What kind of domestic seed industry exists?
- What kind of public breeding sector exists?
- What kind of seed supply system is in place?
- To what extent is farm-saved seed used in the country?
- What is the current capacity of breeders?
- What do local breeders want to do in the next 5-10 years?
- Are external inputs to agriculture low or high?
- What are the country's production needs and objectives?
- What is the country's biotechnology capacity?
- What are the goals and realistic expectations of the biotechnology sector?
- What kinds of strategic alliances will the country want to enter into in the next 5-10 years and how involved will other countries be?

The fact that the answers to these questions will vary widely from one country to another suggests that, as with patents, one size is unlikely to fit all.

3.1 Patents on Plants, plant varieties, seed and other propagating material

As was mentioned above, Plant Variety Protection laws were developed in response to industry calls for sui generis protection for agricultural and horticultural innovation. The inclusion of a seed saving exception for farmers, was a public policy safeguard which was an early reflection of food security concerns. This safeguard does not exist in patent statutes and this absence was an inducement for seed companies to shift their attention to the patent system as a means of protecting their innovations. This attention shift coincided with the development of modern biotechnologies.

Patent protection was not originally considered to be a particularly effective system for the protection of plant varieties. Prior to the development of modern biotechnology, the breeding of a new variety could not be said to involve an inventive step and such innovations as were made, could be considered to be obvious rather than inventive. However with the extension of patent protection to recombinant methods for producing transgenic plants and the resulting products, patents have begun to assume an increasing significance in plant variety protection. The broader ambit of patent rights is a particular advantage of this form of intellectual property protection, covering, as it does, plants, seeds and enabling technologies. PVRs are highly specific to the variety and their scope is limited by reference to the physical (propagating) material itself, combined with the description of the variety given in the documentary grant of the rights

The basis for the patentability of biotechnological innovations was the 4:3 decision of the US Supreme Court whereby patentability of living microorganisms was allowed by the Supreme Court in *Diamond* v *Chakrabarty*[8] which concerned the development of a bacterium genetically engineered to degrade crude oil. The basis of the Supreme Court's decision was that new microorganisms not found in nature were "manufacture" or "composition of matter" within the meaning of s.101 of the US Patent Act and were thus patentable. The general approach which patent offices have taken, following the approach in *Diamond* v *Chakrabarty*, is that gene-sequences are inventions when they have been isolated and purified. A number of patent offices in developed countries have permitted the patenting also of partial DNA sequences and Expressed Sequence Tags (ESTs). The value of the patented invention regarding DNA (isolation or synthetization) lies in the encoded information programming the production of a protein or other substances.

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7 IPGRI, *Key Questions for Decision-makers: Protection of Plant Varieties under the WTO Agreement on Trade-related Aspects of Intellectual Property Rights*, IPGRI, Rome, 1999.

8 447 US 303 (1980).

In Europe the Directive on the Legal Protection of Biotechnological Inventions specifically provides in Article 3.2 that "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature".

Article 53(b) of the European Patent Convention (EPC) excludes plant varieties, as well as "essentially biological processes" from the scope of patentable subject matter. This raises, in the first instance, the definitional distinction between plants and plant varieties. The UPOV Convention defines plant variety in terms of a plant grouping within a single biological taxon of the lowest known rank, which grouping can be:

- defined by the expression of characteristics (such as shape, height, colour and habit) resulting from a given genotype or combination of genotypes;
- distinguished from any other plant grouping by the expression of at least one of the said characteristics; and
- considered as a unit with regard to its suitability from being propagated unchanged

The first consideration of the distinction between plant and plant variety by the Technical Board of Appeal of the European Patent Office (EPO) occurred in 1984 in the *Ciba/Geigy* determination.[9] This concerned a plant which had been treated with a chemical compound to confer on the plant a degree of protection from the toxic side-effects of certain herbicides. The Examination Division had refused the patent application on the basis of Art.53(c). This was reversed by the Technical Board of Appeal, which, applying the definition of plant variety in the UPOV Convention, stated that "Article 53(c), "prohibits only the patenting of plants or their propagating material in the genetically fixed form of the plant variety…Plant varieties in this sense are all cultivated varieties, clones, lines, strains and hybrids".[10] In this case the claims covered merely the application of a chemical treatment and not plant varieties as such.

This approach was applied by the Technical Board of Appeal in the *Lubrizol (Hybrid Plants)* case[11] where the Board held that "the term 'plant varieties' means a multiplicity of plants which are largely the same in their characteristics (i.e. homogeneity) and remain the same within specific tolerances after every propagation or every propagation cycle (i.e. 'stability')"[12] The Board then ruled that as the hybrids in issue were not stable, they did not fall within the excluded category of plant varieties.

The European Biotechnology Directive permits the patentability of inventions concerning plants, where "the technical feasibility is not confined to a particular plant…variety".[13] Patent claims can therefore be made in respect of plant groupings, or as stated in Recital 31 to the Directive,

Whereas a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is not excluded from patentability even if it comprises new varieties of plants.

This qualification was addressed by the Technical Board of Appeal in *Novartis/Transgenic Plant*.[14] The application 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 art.53(b) denied the patentability of an invention which could embrace plant varieties.

In its decision of 20 December 1999, the Enlarged Board of Appeal indicated that it would favour the application because, in substance, it did not involve an application for a plant variety. This determination contains some useful guidance on the legal definition of plant varieties. The Enlarged Board of Appeal

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9 Case T 49/83 [1984] *O.J. EPO* 112.

10 *Ibid.*, at 114-115.

11 Case T320/87 [1990] *O.J EPO* 71.

12 *Ibid* at 79.

13 *Directive on the Legal Protection of Biotechnological Inventions*, Article 4(1) para.2, 98/44/EC [1998] *O.J.* L213/130.

14 [2000] *O.J. EPO* 511.

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 tribunal noted that in the case of PVR an applicant had to develop a plant group, fulfilling in particular the requirements of homogeneity and stability, 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.

Outside Europe the prohibition against the patenting of plant varieties is absent. In the USA for example, the Federal Circuit resolved any potential conflict between patent protection and protection under the Plant Variety Protection Act in its decision in *Pioneer Hi-Bred International Inc. v. J.E.M. Ag Supply Inc.*[15] The defendants objected that Pioneer had obtained both patent protection and 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".

The impact of patenting on food security is illustrated by the recent Canadian Federal Court of Appeal case of *Monsanto Canada, Inc. v. Schmeiser.*[16] This case concerned the cultivation by a farmer of Canola, which contained chimeric genes conferring tolerance to glyphosphate herbicides, which Monsanto had patented. Monsanto had marketed these genes in its product "Roundup Ready Canola". Schmeiser had cultivated Canola derived from plants on his land which he claimed had developed this tolerance from wind-borne genetic pollution. The trial court had found that cultivation of a plant was not an infringement of patented genes contained in that plant, however, the majority of the Federal Court of Appeal agreed with Monsanto that this was infringing use.

Counsel for Schmeiser raised the moral question of whether it was right to manipulate genes in order to obtain better weed control or higher yields. The Federal Court of Appeal ruled that this was a question for Parliament to consider and that the court's job was to "interpret the Patents Act as it stands."[17] The majority explained that, "Under the present Act, an invention in the domain of agriculture is as deserving of protection as an invention in the domain of mechanical science. Where Parliament has not seen fit to distinguish between inventions concerning plants or other inventions, neither should the courts".[18]

As the minority judge pointed out, the TRIPS Agreement in Art.27.2(b) permits the exclusion of plants from patentability, but that plant varieties might be patented. The *Novartis* determination, among others, suggests that the addition or modification of genetic material to confer disease resistance is not the creation of a new variety. If the view of the majority in Schmeiser, that the patenting of a cell confers exclusive patent rights in relation to a plant in which that cell is included, then the Art.27.2(b) exception becomes meaningless.

The Joint Communication of the African Group to the TRIPS Council[19] suggested that Article 29 of the TRIPS Agreement seems to be the most suitable for an appropriate modification to deal with the issue of patenting plant variety rights, by including the requirements for equity, disclosure of the community of origin of the genetic resources and traditional knowledge, and a demonstration of compliance with applicable domestic procedures. Thus the Group suggested that Article 29 be modified by adding the following as paragraph 3:

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15 200 F.3d 1374 (Fed. Cir. 2000), *cert. granted,* 148 L. Ed. 2d 954 (2001)

16 2004 SCC 34, Decision, January 20,2004.

17 Ibid., para. 93.

18 Ibid., para. 94.

19 WTO Doc., IP/C/W/404, 20 June 2003.

3. Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin.

3.2 Patenting and the Research Exception

Plant breeders have tended to stress the necessity of being able to freely access genetic material including that which is IPR protected. This is why the UPOV Convention contains a broad breeders' exemption. Patent law tends to have a much narrower research exemption which is often limited to non-commercial scientific or experimental use.

The narrowness of the research exception in patents law is illustrated by the recent US decision in *Madey v Duke University*[20] which held that a university which undertook commercial research contracts, could not avail itself of the defence. The ambit of the experimental research exception in patents law in the UK was examined in *Monsanto v Stauffer*[21] In that case, Stauffer had developed a market variant 'Touchdown' of Monsanto's successful patented weed-killer 'Roundup' for which they had obtained provisional clearance from relevant authorities. In order to obtain final clearances, Stauffer had established tests at their own research farm and also organised a series of tests outside their research farm where interested parties could observe the results. Monsanto moved for an interlocutory injunction on the grounds of patent infringement, which was granted by the Patents court, negating the ground that tests done outside the research farm to check their product in different soil and climatic conditions, amounts to an experimental use. The Court of Appeal, although it agreed that tests done outside could not qualify for an experimental use exception, exempted all trials carried out at Stauffer's research farm and at laboratories and greenhouses in the UK. The Court limited the interpretation of the word 'experimental' in accordance to its size, scale, recipient and methodology. This case has raised an uncertainty as to how far university researchers could apply the experimental use exception to field trials.[22]

Another aspect of the relative narrowness of the experimental use exception in patents law, compared with plant variety rights protection laws, is that while a protected plant variety is covered by a single title, plant-related biotechnological inventions are likely to be protected by a patent and in some cases several patents. The patents may cover not just plants, but also seeds, genes and DNA sequences. The effect of patents is to restrict access to the patented 'products'. It has been argued that 'locking up' genetic resources with patents is a bad thing because innovation in plant breeding is cumulative and depends on being able to use as wide a stock of material as possible. It was to deal with this concern that the FAO International Treaty introduced a number of provisions as were laid out above.

However, apart from patents, the restrictions on access to breeding material may have other causes than IPRs. For one thing, some countries have chosen to exempt certain categories of plant genetic resources they consider to be strategically important from the multilateral system to be set up under the International Treaty. Also, some developing countries have been exercising their rights under the CBD to regulate access to their genetic resources and in doing so have restricted their free flow. This may well be detrimental to long-term food security even in their own countries.[23]

But beyond these issues about how specific intellectual property rights privatise genetic material needed for breeding is the association of IPRs with the privatisation of agricultural research, the shrinkage of non-proprietarian public sector research, and the increased concentration of ownership of breeding material, research tools and technologies in the hands of a small number of giant corporations.[24] Not only does this trend reduce the free circulation of breeding material, but it can also make public policy making

20 307 F.3d 1351 (Fed. Cir. 2002).

21 [1985] RPC 515 CA.

22 See P. Loughan, 'Intellectual property, research workers and universities' [1996] 6 *European Intellectual Property Review* 351

23 C. Fowler, 'Sharing agriculture's genetic bounty' (2002) 297 *Science* 157.

24 See R.W Herdt, 'Enclosing the global plant genetic commons'. Paper prepared for delivery at the China Center for Economic Research, May 24,1997.

aimed at enhancing food security harder to put into practice. This is because it is much more difficult for governments to influence companies than the public institutions they partly or wholly fund.

3.3 Ethical Issues Relating to the Patentability of Life-forms

There is a substantial literature on the ethical implications of permitting the propertisation of the "building blocks of life" or at least to "reduce the value of life and nature to the merely economic". The Joint Communication of the African Group to the TRIPS Council on taking forward the review of Article 27.3(b) of the TRIPS Agreement[25], stated that patents on life forms were unethical and "contrary to the moral and cultural norms of many societies in Members of the WTO". The Joint communication invoked the exception in Article 27.2 for protecting *ordre public* and morality as a justification to outlaw patents on life forms.

An important question, for which empirical work is required concerns the impact of oligopolisation in the biotechnology market on the capacity of international institutions to provide public goods to developing countries in the agricultural sector. The proprietisation of enabling technologies, as well as genetic resources raises concerns about the capacity of the public agricultural research system to fulfil its public good mission in contributing to the elimination of food insecurity. As Drahos observed, "in biotechnology and agriculture it is likely that much research will end up as an international rather than public good and that it will be distributed according to complex licensing structures."[26]

In addition to the possible adverse impacts this market concentration might have upon the vigour of competition, the market dominance of these private corporations also has an important influence upon 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 as such and away from Southern health problems[27] and Southern food priorities[28]. Will the owners of IPRs in key enabling technologies make them available to public research institutions on affordable terms?[29]

Article.27.2 of the TRIPS Agreement, permits Members to disallow the exploitation of inventions "which is necessary to protect *ordre public* or morality, including to protect human or plant life or health or to avoid serious prejudice to the environment…". Member states would have to show that the commercial exploitation of the specific invention, would be contrary to *ordre public* or morality. In light of the interpretation and application of the equivalent provision within the European Patent Convention, and recently reinforced in the EU Directive on the Legal Protection of Biotechnological Inventions, it is unlikely that this exception would permit a general exclusion of living material from patentability. It is also questionable whether patent offices are the proper bodies to adjudicate the application of moral and ethical issues to the patent system.[30] In any event, the patent offices have abstained from exercising moral judgements in this area. Thus for example in *Greenpeace v Plant Genetic Systems NV,*[31] in an opposition to an application for a patent directed to transgenic plants engineered to be resistant to the herbicide Basta, Greenpeace argued that it was immoral and therefore in breach of Article 53(a) of the European Patent Convention, to "own" plants which were the common heritage of humankind. The Appeal Board of the EPO, sustained the Examination Division's view that it was not the proper forum for discussing the

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25 IP/C/W/404, 20 June, 2003.

26 P.Drahos, The Rights to Food and Health and Intellectual Property in the era of 'Biogopolies' [2002] European Intellectual Property Review

27 J. Watal, 'Pharmaceutical patents, prices and welfare losses: policy options for India under the WTO TRIPS Agreement.' (2000) 23 *The World Economy* 733.

28 J. Alston, G.Pardey and J. Rosenboom 'Financing Agricultural Research: International Investment Patterns and Policy Perspectives' (1998) 26 *World Development* 1045.

29 K.M Leisinger, 'Ethical Challenges of Agricultural biotechnology for developing Countries'. In G.J.Persley and M.M.Lantin, Eds.. *Agricultural Biotechnology and the Poor.* Proceedings of an international conference, Washington DC, 22-22 October 1999. CGIAR.

30 See R. Ford, 'The Morality of Biotech Patents: Differing Legal Obligations in Europe?' (1997) 6 *European Intellectual Property Review* 315; M. Llewelyn, 'The Legal Protection of Biological material in the New Millennium: The Dawn of a New Era or 21st Century Blues' (2000) 4 *Bio-Science Law Rev.* 123.

31 OJ EPO 8/1995 545.

advantages and disadvantages of genetic engineering. Similarly in *Novartis/Transgenic Plants*[32] the Extended Board of Appeal of the EPO considered the debate over genetic engineering to be too controversial for it to sustain Greenpeace's opposition to the patent. The Extended Board of Appeal noted that the European Patent Directive on Biotechnology was an indication that the European Parliament considered there to be some benefit in genetic engineering.

4. The FAO International Treaty on Plant Genetic Resources

Plant genetic resources for food and agriculture (PGRFA) were freely exchanged by the international agricultural research institutes of the CGAIR, as well as by their national counterparts on the basis that they were the common heritage of humankind. This principle was embodied in the International Undertaking adopted by the FAO Conference in 1983. The International Undertaking was adopted as a non-binding conference resolution. In subsequent years the principle of free exchange was gradually narrowed by the impact of intellectual property rights upon agriculture. In November 1989 the 25th Session of the FAO Conference adopted two resolutions providing an "agreed interpretation" that plant breeders' rights were not incompatible with the Undertaking. The acknowledgment of plant variety rights obviously benefited industrialised countries, which were active in seed production. In exchange for this concession, developing countries won endorsement of the concept of "farmers' rights". A further resolution in 1991 recognized the sovereign rights of nations over their own genetic resources. Agenda 21, promulgated at the Rio Earth Summit in 1992 called for the strengthening of the FAO Global System on Plant Genetic Resources. Resolution 3 of the Final Act to the CBD noted that the access to *ex situ* germplasm collections, such as those maintained by the CGIAR, and the realization of Farmers' Rights, were the province of the International Undertaking. The 1993 FAO Conference called on member states to harmonize the International Undertaking with the CBD. Negotiations for revision of the International Undertaking to take account of both the CBD and the TRIPS Agreement commenced in November 1994 and were consummated with the adoption of the International Undertaking as the International Treaty on Plant Genetic Resources for Food and Agriculture.

The objectives of the Treaty are stated in Article 1 to be "the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security".

Article 4 of the Treaty requires signatories "where appropriate" to "promote an integrated approach to the exploration, conservation and sustainable use of plant genetic resources for food and agriculture". Article 10.2 contains the agreement of the Contracting Parties to "establish a multilateral system, which is efficient, effective and transparent, both to facilitate access to [PGFRA] and to share, in a fair and equitable way, the benefits arising from the utilisation of these resources, on a complementary and mutually reinforcing basis". Facilitated access to PGFRA is to be provided in accordance with the conditions prescribed in Article 12.3. Paragraph (d): that the recipients "shall not claim any intellectual property or other rights that limit the facilitated access" to PGFRA, or their "genetic parts or components", in the form received from the Multilateral System. This, of course, does not prevent intellectual property rights being claimed in relation to germplasm which is modified by the recipient.

Article 13.1 recognises that benefits accruing from facilitated access to PGFRA shall be shared fairly and equitably under this Article. Article 13.2 envisages that this sharing of benefits include the exchange of technical information, access to technology, capacity building and the sharing of monetary benefits from commercialisation.

Article 28 provides that the Treaty enters into force, 90 days after accession by 40 countries. Until that date, the International Undertaking will remain operative.

The establishment of the Multilateral System was the principal innovation introduced by the treaty. This asserts the primacy of national sovereignty over biological resources, but in fact imposes limitations on countries on their ability to restrict access to other states. Facilitated access has to be provided to the crops listed in Annex I, which account for a significant part of human nutrition. Member states are obliged to

[32] Decision G0001 of 20 December 1999.

make available all passport data and, subject to applicable law, any other associated non-confidential descriptive information. In relation to material which is under development by farmers or breeders at the time when access is requested, the Treaty gives the country of origin the right to delay access during the period of development. Two compromises were necessary to secure this right of access: first, is the limitation imposed by Article 12 upon recipients seeking intellectual property rights in material obtained under the Treaty; the second was the right of donors to receive some form of benefit sharing. Benefit sharing mechanisms under the Treaty include: the exchange of information, access to and transfer of technology, capacity building, and the sharing of the benefits arising from commercialisation.

The CGIAR Centres had signed agreements with the FAO in 1994, placing the acquisitions to their germplasm collections after that date under the trusteeship of the FAO. Under the Treaty, new agreements were invited, to determine that the access provisions of the Treaty would govern the germplasm collections of the Centres which fell within Annex I list, collected after the entry into force of the Treaty.

5. Farmers' Rights and Food Security

Article 9 of the International Treaty on Plant Genetic Resources for Food and Agriculture implements the proposal which was developed under the International Undertaking for the recognition of farmers' rights. The policy behind this recognition is stated in Article 9.1, namely that

The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.

The principal contribution of traditional farmers to agrobiodiversity has been their conservation of landraces, which are crop varieties that are primitive cultivars, developed by local farmers to deal with the local climate and diseases and to cater to local tastes and food-preparation practices.[33] This development may involve the interbreeding of locally occurring undomesticated plants with cultivated plants, as well as the exchange of different genotypes among farmers and farms.[34]

6. Traditional Knowledge and Food Security

A significant contribution has been made by the knowledge of indigenous peoples and traditional farmers in the development of new crop types and biodiversity conservation. These groups have been an important agency in the conservation of plant genetic resources and the transmission of these resources to seed companies, plant breeders and research institutions. They have not typically been paid for the value they have delivered, whereas breeders and seed companies have resorted to intellectual property rights to recover their development expenditures. On the other hand, farmers who utilize improved varieties are obliged to pay for them.

The economic value of biological diversity conserved by traditional farmers for agriculture is difficult to quantify. It has recently been suggested that "the value of farmers' varieties is not directly dependent on their current use in conventional breeding, since the gene flow from landraces to privately marketed cultivars of major crops is very modest" [35] because "conventional breeding increasingly focuses on crosses among elite materials from the breeders own collections and advanced lines developed in public institutions." On the other hand, those collections and advanced breeding lines are often derived from germplasm contributed by traditional groups.

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33 See S.B. Brush, .ed. *Genes in the Field: On-Farm Conservation of Crop Diversity.* Rome, Ottawa, etc: IPGRI, IDRC, and Lewis Publishers, 2000.

34 See P. Wright, P. 'Intellectual Property and Farmers' Rights' in R. Evenson, D. Gollin and V. Santaniello, Eds. *Agricultural Values of Plant Genetic Resource*s. 1998, Wallingford, CABI.

35 C. Correa, *Options For The Implementation of Farmers' Rights at The National Level*, South Centre, Trade-Related Agenda, Development And Equity Working Papers, No. 8, December 2000, citing Wright, 'Intellectual Property and Farmers' Rights' in R. Evenson, D. Gollin and V. Santaniello, Eds., *Agricultural Values of Plant Genetic Resource*s, Wallingford, FAO/CEIS/CABI, 1998, 228.

An increasingly significant economic value of biodiversity is the extent to which it provides a reservoir of species available for domestication, as well as genetic resources available for the enhancement of domestic species. The modern biotechnological revolution has enabled the engineering of desirable genetic traits from useful local species. It is estimated that about 6.5% of all genetic research undertaken in agriculture is focussed upon germplasm derived from wild species and land races.[36]

Traditional knowledge is particularly important in the development of farming systems adapted to the local conditions, and farming practices. This may enable the utilisation marginal lands, contributing to food security in enabling access to food in remote areas, as in contributing to the management of the environment by, preventing erosion, maintaining soil fertility, and agrobiodiversity[37].

Article 9.2 of the FAO International Treaty on PGRFA envisages that "the responsibility for realizing Farmers' Rights, as they relate to Plant Genetic Resources for Food and Agriculture, rests with national governments" and that national legislation should include measures relating to: "(a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture". Traditional knowledge has played an important role in assuring food security for subsistence communities. Farmers in subsistence systems have tended to utilise a diverse selection of crop species in order to assure their annual harvests and thus to guarantee a minimal level of production and to prevent food shortage. Seed production in many instances has been on the collection of and domestication of locally known, wild varieties. Modern agricultural practices depend on crop species that promote productivity and resistance to disease that can only be maintained with the continuous input of new germplasm. The diversity of landraces and the associated information on their specific qualities contribute invaluable information to formal breeding processes. It has been noted that the loss of biological diversity is paralleled by the loss of traditional knowledge. Where a plant variety becomes extinct, then the entire body of knowledge about its properties is condemned to irrelevancy.

Finally, Article 9.3 provides that the Article shall not be interpreted "to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material".

An assumption of Article 9.1 is that the landraces used by traditional farmers are a dynamic genetic reservoir for the development of new varieties and for the transmission of desirable genetic traits. The traditional knowledge of local and indigenous communities is similarly perceived. As a means of remunerating these groups for their past contributions to the development of plant genetic resources for food and agriculture production, there can be little argument, except about the quantum and distribution of this remuneration.

Inevitably, any calculation of the equitable share, which traditional farmers and indigenous communities might enjoy under a Farmers' Rights, or Traditional Knowledge regime will be arbitrary. However the intellectual property system is no stranger to arbitrary calculations, thus the 20 year length of a patent term is intended to provide an opportunity for the compensation of all inventors, whatever the area of technology. Similarly the 25 years exclusivity which the UPOV Convention provides for new varieties of trees and vines, takes no account of variations in R & D costs between the different varieties.

The principal ways in which plant genetic resources are translated into food and agriculture production is through plant breeding and plant patenting. Standing at the heart of a Farmers' Rights regime is the concept of the equitable sharing of benefits with farmers for their contribution to innovations in plant breeding and plant patenting.
Article 9.2 obliges the Contracting Parties to the Plant Genetic Resources Treaty "to take measures", subject to their national legislation to protect and promote Farmers' Rights. The content of these rights is defined in the balance of that provision and embraces the protection of traditional knowledge, equitable

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[36] McNeely, 'Biodiversity and Agricultural Development: The Crucial Institutional Issues' in D.R.Lee and C.B.Barrett, Eds, Tradeoffs or Synergies? Agricultural Intensification, Economic Development and the Environment, Wallingford, CABI, 2001, 399 - 408.

[37] See C. Fowler, C. M Smale and S Gaiji. 'Unequal Exchange? Recent Transfers of Agricultural Resources and their Implications for Developing Countries' (2001) 19 *Development Policy Review* 181.

benefit sharing and the right to participate in decision making. The Treaty leaves open the legal context within which Farmers' Rights are to be enacted.

National legislation on Farmers' Rights tends to combine one of the versions of UPOV with some of the access principles of the CBD. The African Model legislation for the Protection of the Rights of Local communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, which was adopted by the OAU, Heads of States Summit at Ouagadougou in June 1998, adopts a *sui generis* regime based on UPOV 1991. However, most national statutes prefer access legislation combined with UPOV 1978 (eg Andean Community's Common System on Access to Genetic Resources, 1996; Costa Rica- Biodiversity Law 1998; India- Community Intellectual Property Rights Act 1999; Kenya- Seeds and Plant Varieties Act 1975).

7. Assessment of the Relationship Between IP and Food Security

The role of intellectual property in eliminating food insecurity has to be placed in its proper policy perspective. Development experience over the last 50 years attributes rural poverty and food insecurity in developing countries to development strategies that overlooked the importance of the development of the agricultural sector, particularly the production of staple foods. [38] Thus the enhancement of food security in developing countries requires a package of policies that address the supply, distribution and consumption aspects of the food chain. The FAO has noted that the policy options which are available to poor countries are constrained by a number of factors including: (a) limited resources for public spending programmes; (b) the dilemma between remunerative prices for producers and prices that a large number of poor households can afford, thus making the option of border protection less attractive, despite high bound tariffs; (c) major constraints on foreign exchange availability leading to pressure to boost production of export crops.[39]

Where intellectual property could make its greatest contribution is in the incentivisation of beneficial agricultural innovations. Historically, the strongest incentives have been those arising from the marketing of hybrid seeds, which provide higher yields, with the commercial benefit to the seed marketer that the seeds of the offspring cannot be used by the farmer because these seeds do not breed true-to-type. As is discussed above, the evidence for incentives to breeding research for crop plants is limited and in developing countries, it is even more questionable, whether PVP and patenting will be useful in encouraging a national seed industry. Barton suggests that a developing country "is probably best-off adopting minimum compliance with TRIPS, which requires at least some form of *sui generis* protection for plants – although there is the possibility that a number of nations with similar agricultural conditions could combine their markets in some way that encouraged private investment. Moreover, use of UPOV-style laws might help in commercializing varieties developed by the public sector."[40]
The question of whether a developing country will adopt a *sui generis* PVP system or a patent-based system, to comply with Article 27.3(b) of the TRIPS Agreement will depend upon the technological sophistication of agricultural research in that country.

38 See R. McNeely, 'Biodiversity and Agricultural Development: The Crucial Institutional Issues'. In D.R.Lee and C.B.Barrett, Eds. *Tradeoffs or Synergies? Agricultural Intensification, Economic Development and the Environment*. Wallingford, CABI, 2001, 399-408.

39 *The State of Food and Agriculture: Lessons from the Past 50 Years*, FAO, Rome, 2000.

40 FAO, *Incorporating food security concerns in a revised Agreement on Agriculture*, FAO Round Table on Food Security in the Context of The WTO Negotiations on Agriculture, 20 July 2001, Discussion paper no. 2.