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Plant Genetic Resources for Food and Agriculture: Facilitated Access or Utility Patents on Plant Varieties?

Walter Smolders

An Overview of Plant Variety Protection in South Africa

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Executive Summary

Intellectual Property systems, more specifically Patent and Plant Variety Protection systems, vary by country. In compliance with TRIPS, it is generally accepted practice for countries to adapt their IP legislation to their socio-economic needs. Appeals from certain circles for a global revision of the UPOV Convention are accordingly not well founded.

Because industry investment in countries is not determined by strong IP protection but by promising market potential, this paper argues that it is more important to facilitate access to plant genetic resources and to transfer technology to developing countries than to strengthen the global system of intellectual property rights. Indeed, patent protection for plant varieties *per se* is inappropriate from a global perspective, especially for developing countries, but the same may be true for the United States.

Considering some key examples, this essay criticizes the practice of patent drafting for inventions directed to new plant varieties in the United States and shows that several claim categories of utility patents for plant varieties are questionable. It also concludes that the examination of such patent applications and the enforceability of several claim categories are problematic. At the very least, serious consideration should be given to the issuance of guidelines for disclosure requirements and more stringent evaluation standards for determining whether a patent claim on a plant variety is obvious. This is considered essential to rebalance the rights to plant varieties granted by utility patents with a contribution to society.

1. Intellectual Property Rights: Diversity within a TRIPS Framework

In not more than 8 Articles the TRIPS Agreement provides a general framework for Patents that considers all of the following: the minimum requirements for patentable subject matter, the exclusive rights a patent must confer, patent disclosure conditions, what limited exceptions to exclusive patent rights may be conferred, and the conditions under which the subject matter of a patent may be used without the holder's authorization. TRIPS also mentions briefly that Members shall provide protection for plant varieties by patents, by an effective *sui generis* system, or by any combination thereof. It does not go into detail about the criteria for an effective *sui generis* system or about how to combine such a system with a patent system.

1.1 Diversity in the Patent World

The US Patent and Trademark Office (USPTO), the European Patent Office, and the Japanese Patent Office exchange some information about their examination practices, but this is hardly harmonization. The differences in patent law and practice between the USA and the EU, for example, are real and unlikely to change soon. Such differences include:

- The USA has a first to invent principle while nearly all other countries have a first to file system.
- The European Patent Convention (EPC) provides for absolute novelty requirements, the US Patent Act does not.
- A novelty grace period exists in the US but not in the EPC.
- The EPC has a research exemption, the US essentially does not.
- Before the US issues a patent, microorganisms must be deposited according to the Budapest Treaty; in most other countries this happens before the filing date of the patent application.
- The reexamination procedure in the US and the opposition procedure before the EPO differ substantially.
- Business schemes can be patented in the US but not in Europe.

Despite TRIPS and patent systems that are several hundreds years old in some countries, a global patent system remains very far away. Indeed, the minimum requirements laid out by TRIPS leave a lot of room for Members to adapt their patent act to local needs.

Of particular relevance is Article 8.1 of the TRIPS Agreement:

> Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

This Article was not solely created to benefit developing countries, as is illustrated by the Waxman Hatch Act, introduced in the US in 1984 as a quick reaction to the Roche v. Bolar court decision in 1983. The Act exempts experiments on patented drugs and medical devices carried out for the purposes of obtaining FDA approval. This example shows that developed countries also introduce exemptions for patent infringement when such exemptions benefit local industry.

1.2 Diversity in the plant variety IP protection world

Compared to the patent system, the International Union for the Protection of New Plant Varieties (UPOV) is very young. Adopted in 1961, it was supplemented by an Additional Act adopted in 1972, underwent a comprehensive revision in 1978, and a second comprehensive revision in 1991. Of the 55 member states, 2 states (Belgium and Spain) are still party to the 1961/1972 Act; 25 states, including developed countries such as Canada, France, Ireland, Italy, New Zealand, Norway, and Switzerland are party to the 1987 Act; 28 states are party to the 1991 Act.

Plant variety protection laws of candidate UPOV members are being reviewed for UPOV conformity and several countries are in the process of implementing UPOV conforming plant variety protection systems. Other national *sui generis* plant variety protection systems are in place or are being developed.

The breeder's exception is the cornerstone of the UPOV Convention and is common to all UPOV Acts. It exempts acts done for the purpose of breeding from the Breeder's right. The various Acts differ, however, in terms of the number of species to be protected, the scope of protection, and the minimum term of protection. Further, national laws and their implementation vary from country to country for any given Act. The TRIPS agreement offers even more flexibility for protection of plant varieties. Indeed, the present TRIPS criteria for a *sui generis* system to protect plant varieties are extremely loose: the sole requirement is that it must be effective. Accordingly, several national laws exist or are being prepared that may be incompatible with UPOV.

Obviously, for practical and other reasons it would be desirable to have a global agreement on the minimum requirements for all *sui generis* systems for protecting plant varieties.

The major stumbling block for states to join UPOV is believed to be its farmers' privilege provision. As with the patent system, however, Contracting Parties of the UPOV Convention can adapt their national laws to the socio-economic needs of their country.

Indeed, even developed countries have very creatively interpreted Article 15(2) of UPOV 1991, which authorizes Contracting States to restrict breeder's rights "within reasonable limits and subject to the safeguarding of the legitimate interest of the breeder" in order to permit farmers under certain conditions to save the product of the harvest on their own holdings. For example, EC Regulation No 2100/94 on Community Plant Variety Rights distinguishes between small-scale farmers and other farmers. For producers of certain arable crops, small-scale farmers are defined as cultivating an area no bigger than that required to produce 92 tonnes of cereals (Art.14(3) of the Regulation). Small-scale farmers using,

> "for propagation purposes in the field, on their holding the product of the harvest which they have obtained by planting, on their own holding, propagating material of a variety other than a hybrid or a synthetic variety, which is covered by a Community plant variety right" (Art. 14(3) of the Regulation),

are not required to pay any remuneration to the holder of the plant variety right. Other farmers are required to pay an equitable remuneration to the holder, which however

> "shall be less than the amount charged for the licensed production of propagating material in the same area" (Art.14(3) of the Regulation).

The US Plant Variety Protection Act (PVPA) is even more generous to farmers. It does not require any remuneration from farmers for saving, on their holding, seeds that they obtained by planting the protected variety on their holdings. This is clearly not in compliance with the UPOV requirement to safeguard the legitimate interest of the breeder, a requirement that the US PVPA regretfully avoided incorporating in its revised 1994 PVPA. It is difficult to see how the socio-economic situation in the US necessitates this farmer-friendly interpretation, not least because farmers are not authorized to save seeds if the same variety is protected by a US utility patent.

To meet the needs of developing countries, UPOV Article 15(2) may require some creative interpretation of the phrase "on their own holdings," bearing in mind that subsistence farmers do not necessarily own the land they are cultivating. It would also appear that there is room for interpretation of the UPOV view that activities of subsistence farmers, where these constitute acts done privately and for non-commercial purposes, are excluded from the scope of the breeder's right and such farmers freely benefit from the availability of protected new varieties (UPOV C/37/20, Annex II).

Indeed, although UPOV provides that the breeder's right does not extend to "acts done privately and for non-commercial purposes," it is not clear whether the common practice of subsistence farmers exchanging harvested material within their community would be in line with that provision. Of course, given the fact that there is substantial room for interpretation of UPOV Article 15(2), and given the socio-economic needs of developing countries, particularly Least Developed Countries, such countries have the authority to exempt certain activities of subsistence farmers from infringement.

The issue of whether smallholder farmers following their traditional patterns of local exchange are engaged in private and non-commercial uses was recently raised at a meeting organized by the International Plant Genetic Resources Institute (IPGRI) and UPOV (press communication "IPGRI and UPOV find common grounds"). This is encouraging, and it was agreed that "IPGRI will make technical contributions on this issue to UPOV's Administrative and Legal Committee, based on its *in situ* conservation projects with smallholder farmers."

In the long term, we should strive for one global framework for a *sui generis* system of plant variety protection. UPOV can play an important role. It can continue dialoguing with Associations and Institutes that aim to build bridges with countries that protect or aim to protect plant varieties with a *sui generis* system that differs from the UPOV.

Although many countries exclude plant varieties *per se* from patent protection, several countries, including the US, Japan, and Australia, grant such protection. In the US, the Supreme Court confirmed that plant varieties are patentable subject matter and that it is possible to protect a plant variety by utility patent and by the Plant Variety Protection Act (J.E.M. AG Supply v. Pioneer Hi-Bred). Although this is in compliance with TRIPS, it is the author's conviction that neither patents nor a patent-like system are appropriate for protecting plant varieties *per se* (see below, section 4.3). This is particularly true for developing countries.

1.3 Implementation of TRIPS and UPOV 1991

Developing country members of the WTO have been obligated to implement TRIPS-level protection in their national laws since 1 January 2000. Many of those countries, however, have not yet fully implemented the TRIPS Agreement. Some of them, such as Egypt and India, had until 1 January 2005 to apply the patent provisions of the TRIPS Agreement to pharmaceutical and agricultural chemical products. The Least Developed Country members of the WTO originally had a deadline of 1 January 2006 to implement the whole agreement, but they were granted an extension to 1 January 2016 to implement or apply Sections 5 (Patents) and Section 7 (protection of undisclosed information) with respect to pharmaceutical products (Paragraph 7 of the Doha Declaration on TRIPS and Public Health (November 2001)).

The UPOV Convention 1991 provides for a transition period during which new member states could deposit an instrument of accession to the Act of 1978. This transition period has since expired, and new candidate UPOV members can only join the UPOV 1991.

It should not be forgotten, however, that the 1991 Act offers flexibility for new members in terms of genera and species protection: they need to apply the conditions of the 1991 Convention to only 15 plant genera or species during the initial 10 years of their membership. It would also be advantageous for developing countries to have UPOV 1991 protection by carefully designating the plant genera and species (e.g., selection of indigenous food and staple crops). Indeed, because the UPOV 1991 Act allows for the protection of varieties essentially derived from a developing country's indigenous crops, these countries can initially build up strong protection around their indigenous crops while delaying the protection of import crops. The need for strong IP rights spontaneously develops in countries with the technological capabilities to create local industry and markets. To put it rather bluntly, the technology comes first and strong IP protection follows inevitably.

2. Must Intellectual Property Rights (IPR) be strengthened globally?

A recent American Seeds Trade Association (ASTA 2004) news release expressed concern that "open access to germplasm allowed under UPOV for breeding immediately upon commercialization has the effect of diminishing the developer's opportunity to earn a competitive return on research investments".

Among other action points, ASTA suggests that we

1) maintain the effectiveness of the utility patent system and

2) strengthen the UPOV/PVP system by:
   - Providing compensation for and/or limits on saved seeds in all countries
   - Making the Essentially Derived Varieties (EDV) system more effective
   - Revising the breeders' exemption to include a period of "x" years (where x varies by crop) for which the breeders' exemption would not be available for PVP protected material.

The issue of the "effectiveness of the utility patent system" regarding protection for plant varieties is discussed in section 4.3.below.

With regard to the UPOV Convention, as previously mentioned, every country has the authority to adapt its national law to its socio-economic needs. National conditions for farm-saved seeds can therefore be made more stringent when appropriate, and the EDV system can be made more effective within the framework of the UPOV Convention.

The revision of the breeders' exemption, however, would require a review of the UPOV Convention. Before making an amendment proposal to fundamentally change an international convention, it is appropriate to consider whether it will benefit three-quarters of the UPOV States members present. Indeed, amendments to the UPOV Convention require a three-quarters majority of the Member States present for adoption.

New sophisticated technologies, such as marker assisted breeding, can speed up breeding processes and facilitate the development of competitive "me too" varieties. These technologies are available to research-based seed companies, but most if not all of them are based in developed countries. It would therefore appear that efforts to "strengthen" the UPOV system aim primarily to maintain the *status quo* of germplasm ownership for technologically highly advanced companies disposing of an important private seed bank, which strengthens their defense against technologically advanced "me too" breeders. While this may be worthwhile in developed countries, it is not for developing countries.

Consider what the report by the Commission on Intellectual Property (CIPR 2001) on Integrating Intellectual Property and Development emphasizes:

> Standards of IP protection that may be suitable for developed countries may cause greater costs than benefits when applied in developing countries which must rely in large part on knowledge of products embodying knowledge generated elsewhere to satisfy basic needs and foster their development…. [D]eveloping countries should not be deprived of the flexibility to design their IP systems that developed countries enjoyed in earlier stages of their own development, and higher standards should not be pressed on them without a serious and objective assessment of their development impact.

The UPOV requirement for candidate members to adhere to the UPOV 1991 Act is already a very high burden, and introducing even more stringent protection requirements in the near and mid term future appears undesirable. We must remember history:

> The absence of such [intellectual property] rights has often facilitated enormous economic wealth, which, after a period of "copying" often leads to private research and development investments (The Crucible II Group 2002).

This is true of Japan, Switzerland, and the US, all of which gradually strengthened their intellectual property laws to improve the protection of their local industry's increasing R&D investments.

Although industry invests primarily in markets that will offer a return on investments, in the initial stage of technology development the strength and enforceability of IPRs are welcome but not essential. Much more important are potential market size, local infrastructure, the availability of skilled people to adapt new technologies invented in developed countries to local needs, and the existence of an appropriate biosafety legislation and administration when Living Modified Organisms (LMOs) are involved. For example, industry seems more interested in entering the GM cotton market in India than in Mali; India, however, had untill 1. January 2005 no patent protection for products. The African Intellectual Property Agreement (OAPI) created by the Bangui Agreement[2], of which Mali is a member, provides patent protection for products since March 1977.

Despite inadequate protection, the Roundup-Ready™ (RR) cotton market in India is exploding: from 72,682 acres in 2002 to 1,292,000 acres in 2004 (Barwale 2004). One reason for this commercial success is certainly the availability of local licensees capable of introgressing the RR technology in Indian varieties. As commercial success of new technologies attracts competitors, the need to protect local industry's R&D investments increases. Aware of the value of agricultural biotechnology for the country and for local industry, the Indian Government also recognizes the need for action against producers and

[2] www.eldis.org/static/DOC2286.htm

distributors of "illegal" GM cotton on the Indian market. As a result, India brought its patent act in line with TRIPS effective as of 1 January 2005. Of course, illegal markets can also impair product quality; in this respect enforceable patents also contribute to quality and thus consumer interests.

The IPR situation for Mali and other Contracting Parties of OAPI is different. The 16 OAPI countries have a modern patent law by virtue of the Bangui Agreement. Annex X of that Agreement meets the condition for accession to the UPOV Convention (the 1991 Act) as stated in the annual report of the UPOV Secretary-General for 2002 (C/37/2). The infrastructure is not fully in place, however, and so OAPI decided to postpone implementation. OAPI is accordingly not a member of UPOV.

The EU and particularly the French government are willing to assist training OAPI administrators and examiners, and the Community Plant Variety Office (CPVO) is committed to help develop test guidelines to examine the 15 plant genera or species that OAPI must designate when it becomes bound by the UPOV Convention (Article 3(2) of UPOV 1991). But OAPI has limited resources, limited staff, and the OAPI countries have many other problems (including subsidies for US, Greek, and Spanish cotton producers) with higher priority than implementing Annex X of the Bangui agreement. This situation illustrates the problems developing countries are confronted with when trying to meet the TRIPS requirements.

These examples and citations of authoritative reports provide convincing arguments against strengthening the UPOV system. Even those not completely convinced by the evidence should consider the ASTA proposal to revise UPOV with care.

3. Access to plant genetic resources

3.1 The need for facilitated access to plant genetic resources

Regarding access to genetic resources and IP protection of plant varieties Troyer and Rocheford (2002) observe that "plant varieties are products of many distinct genetic materials, usually developed over a long period of time. Some pedigrees involve 50 or more parents and are literally meters long using standard size type." This makes them wonder: "Who gets credit?" We should all wonder with them.

In his review of "Background of US Hybrid Corn" Troyer (2004) describes the early days:

> All companies started with the same public inbreds, and surviving companies self-pollinated superior competitors' hybrids to develop newer inbreds. … If the goal is to increase market share, it is logical to use breeding material (commercial hybrids) that increased market share. Product performance is heritable (Troyer 2004).

Indeed, in the early days the private sector relied heavily on public lines for the development of new plant varieties. This is particularly true for field crops such as corn:

> Inbreds B14, B73 and Mo17 were popular public inbred lines. They were products of a previous area when Agricultural Experiment Stations, supported by public funds, devoted significant effort to developing superior inbreds. Iowa State used population improvement and early testing in Stiff Stalk Synthetic to develop three very popular inbreds: B14, B37 and B73 (Hallauer *et al*. 1983)

In fact, many inbreds presently used by industry are Essentially Derived Varieties (EDVs) that have had the rights and privileges of Initial Varieties (IVs). In the light of these and other historical facts, Gouache (2004) in a presentation in Berlin contended that if today's intellectual property practice had been in place 30 years ago, then it would be very unlikely that US corn yields would have reached to-

day's level. Indeed, many varieties and inbred lines are derived from varieties developed by the public sector and/or in multiple countries. This illustrates both the value and importance of access to plant genetic resources as well as the interdependency of all countries on such access. This is true for many other crops.

Consider, for example, the genetic ancestry of rice variety IR64. Developed by the International Rice Research Institute (IRRI), it consists of twenty landraces from eight countries, including China, Korea, India, Indonesia, and Vietnam (Kerry ten Kate and Laird 1999). It is therefore understandable that *The Times of India* (2002) wondered in an article about access to rice germplasm: "So whose rice is it anyway?"

Likewise, by the early 1990s, one-fifth of the total US wheat acreage and virtually all the spring-wheat cropped in California were sown to varieties with ancestry developed by the International Maize and Wheat Improvement Center (CIMMYT) (Pardey 2003). Whose wheat is it anyway?

Another example is provided by a Pioneer brand maize hybrid currently grown in commercial agriculture in France. The pedigree background is: Reid Yellow Dent (15%), Flint OP (15%), French Pyrenees Flint (13%), SmithTC (10%), Pioneer Female Composite (8%), European Flint (7%), Leaming (6%), Lancaster Sure Crop (4%), Argentinean Maize Amargo (3%), D107 (3%), Midland (2%), Minnesota 13 (2%), Clarage (1%), and Lindstrom ear (1%) (Smith 2004).

Keep in mind that Ghana, according to an FAO study, is just as dependent on crops originating outside Ghana, as Italy is on crops originating outside of Italy.

Who benefits most from this interdependency? The big innovation for rice and wheat in the 1960s and 1970s was the increasing number of semi-dwarf varieties. National and international research agencies bred these using plant material and crop transformation techniques that were entirely public domain. Almost all the resulting improved varieties were made available without personal or corporate intellectual property rights. The public sector performed most of the research, and Intellectual Property Rights over the varieties themselves or the techniques used to transform them were legal in only a few jurisdictions (Pardey 2003). In fact, the US Plant Patent Act (on asexually reproduced plants) dates from 1930, the first UPOV Convention dates from 1961, and the first utility patents on plant varieties in the United States were filed in about 1985.

Pardey *et al*. (1996) estimated that from 1970 to 1993 the US economy gained US$3.4–$14 billion (depending on the benefit attribution methods deployed) from the use of improved wheat varieties developed by CIMMYT. In the same 23-year period, they found that the U.S. economy realized at least $30 million and as much as $1 billion through the use of IRRI rice varieties.

It will be no surprise, therefore, that UPOV is convinced of the need to provide access to plant genetic resources. In its reply to the Executive Secretary of the Convention on Biological Diversity, UPOV made the following statement on Access to Genetic Resources (see C/37/20 Annex II, adopted by the Council of UPOV at its thirty-seventh ordinary session on October 23, 2003):

> UPOV considers that plant breeding is a fundamental aspect of the sustainable use and development of genetic resources. It is of the opinion that access to genetic resources is a key requirement for sustainable and substantial progress in plant breeding. The concept of the "breeder's exemption" in the UPOV Convention, whereby acts done for the purpose of breeding other varieties are not subject to any restriction, reflects the view of UPOV that the worldwide community of breeders needs access to all forms of breeding material to sustain greatest progress in plant breeding and, thereby, to maximize the use of genetic resources for the benefit of society.

It is rather ironic that the Convention on Biological Diversity (CBD), aiming for access and benefit sharing, accomplished the opposite. Germplasm access became more difficult and complicated than it was

before the CBD was in force. Without access to genetic resources, there is no benefit sharing. It is therefore gratifying for all stakeholders in plant genetic resources for food and agriculture that the International Treaty on Plant Genetic Resources for Food and Agriculture entered into force 29 June 2004 (The Treaty 2004).

3.2 International Treaty on Plant Genetic Resources for Food and Agriculture

The Treaty is more attractive than the CBD because it relies on a multilateral system (MLS) that will facilitate its implementation substantially.

The MLS covers Plant Genetic Resources for Food and Agriculture (PGRFA) listed in Annex I to the Treaty that are under the control of the Contracting Parties (CPs) and in the public domain. It also covers *ex situ* collections of International Agricultural Research Centers of the Consultative Group on International Research (CGIAR). CPs also agree to take appropriate measures to encourage natural and legal persons within their jurisdiction who hold PGRFA to include such PGRFA in the MLS (Treaty Article 11).

Facilitated access is provided to the CPs and to legal and natural persons under the jurisdiction of any CP solely to use and conserve for research, breeding, and training for food and agriculture, as pursuant to a standard Material Transfer Agreement (sMTA) to be adopted by the Governing Body, which is composed of all CPs (Treaty, Article 12). An appropriate sMTA is a prerequisite for an effective, fair, and equitable share of the benefits arising from commercialization. Discussions on the sMTA for the Treaty are ongoing, and it is hoped that they will be constructive and pragmatic. The goal should not be perfection but a workable sMTA.

Benefits accruing from facilitated access shall be shared fairly and equitably through information exchange, technology access and transfer, capacity building, and the sharing of gains arising from commercialization. Farmers in all countries should benefit from using PGRFA shared under the MLS, but especially those in developing countries and countries with economies in transition that conserve and sustainably utilize PGRFA (Art.13.3).

Monetary benefits generated under the Treaty will go into a "mechanism" and dispersed to support PGRFA conservation and utilization programs, primarily in developing countries. It remains to be seen, however, whether the monetary flow resulting from mandatory payments in compliance with the Treaty will be sufficient to meet the objectives of the Treaty. Article 13.2(d)(ii) of the Treaty states,

> a recipient who commercializes a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System, shall pay to the mechanism referred to in Article 19.3f, an equitable share of the benefits arising from the commercialization of that product, **except** whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment.

The initial intention of this Article appears to have been to explicitly recognize that access in itself is a benefit and that a payment should be mandatory whenever the developer of a New Product is unable to freely commercialize it. There will be no mandatory payment, however, whenever the recipient allows research and breeding with its product. Many patent laws provide for a Research Exemption and accordingly allow research and breeding with patented material. Nonetheless, such a Research Exemption does not authorize a person using the product and developing a New Product from it to freely commercialize the product. As Troyer (2002) states, "Research exemption may leave the public sector breeder in the difficult position of developing technology that he may not be able to use."

Should the monetary flow to the "mechanism" be unsatisfactory—a not unlikely prospect—then the Governing Body of the Treaty may "assess, within a period of five years from the entry into force of this Treaty, whether the mandatory payment requirement in the MTA shall apply also in cases where such

commercialized products are available without restriction to others for further research and breeding" (Article 13.2.(d)(ii) of the treaty, 2nd paragraph). The CP can also implement a funding strategy that includes the financial benefits arising from commercialization as a component.

The establishment of the Global Crop Diversity Trust is another component of the funding strategy; it aims to ensure the long-term conservation and availability of the PGRFA. The initial target for the endowment is $260 million, a sum estimated to support Annex I crop conservation. Funds are being raised from governments (70%), foundations (15%), the corporate sector (10%), and private individuals (5%). Approximately $33 million has been pledged to date in expressed commitments and another approximately $60 million is under discussion (Geoffrey Hawtin, pers. com). CP that are developed countries also commit to provide financial resources to implement the Treaty through bilateral, regional, and multilateral channels.

4. Patenting Plant Varieties, technology transfer and capacity building

4.1 The need for technology transfer to developing countries

The Treaty's funding strategy is a very welcome, badly needed initiative of *potential* benefit to developing countries, but these same countries urgently need capacity building and access to modern technology *now*. The big technology gap between developed and developing countries grows wider every day. Can intellectual property rights facilitate technology transfer?

In his presentation "Creating, Protecting, and Using Crop Biotechnologies Worldwide in an Era of Intellectual Property" (Geneva, October 23, 2003), Philip Pardey reminds us that crop improvement was and largely remains a cumulative or sequential innovation process. New varieties are built upon the selection and breeding efforts of farmers and scientists of the past. The cumulative nature of this process means that past discoveries and related research are an integral part of contemporary innovations. Indeed, a great deal of technological change flows from cumulative innovation processes: the fruits of innovation frequently depend upon a sequence of prior innovations. Accordingly, Pardey expressed concern that both crop varieties themselves and tools for crop development are increasingly encumbered by intellectual property. It is an open question whether these changing market, scientific, and intellectual property regimes will help or hinder efforts to develop and disseminate varietal technologies in the future—especially the crop innovations required by the developing world.

By the mid-1990s, about one-third of the $33 billion total public and private agricultural research investment worldwide was private. Little of this research takes place in the developing world. The overwhelming majority ($10.8 billion or 94% of the global total in 1995) is conducted in developed countries, where private funds make up over half of all expenditures. In developing countries the private share is just 5%, and public funds are still the major source of support. In 1995, developed countries spent $5.43 on public and private agricultural R&D for every one hundred dollars of agricultural output. For the same output developing countries spent just 66 cents. This eightfold difference clearly illustrates the enormous size of the technological gap in agriculture between rich and poor countries.

Agricultural R&D funded by private industry has increased in rich countries. But many biotech companies are uninterested in pursuing technologies for applications valuable to many less-developed countries. Moreover, even when such technology is available, they are often not interested in pursuing potential markets in these countries. At that same WIPO-UPOV Symposium, Ochem (2003) illustrated the need for technology transfer:

> Many indigenous food-crops that feed a large percentage of the African population (such as yams, millet, sorghum and cassava) represent little commercial interest to the multinational companies that invest in R&D. Thus, the extension of modern biotechnology tools to the improvement of these food crop species have been minimal, and in some cases, non-existent.

4.2 Modern breeding technologies

Do the many utility patents issued for plant varieties in the US teach scientists how to improve their breeding techniques? Given the following statements showing that the research-based seed industry routinely uses sophisticated breeding techniques to create new plant varieties, the answer appears to be that "They should."

Indeed, plant breeding has dramatically advanced in terms of efficiency and speed, new capabilities, and possibilities. The predictability of outcomes has improved and the introgression of unadapted germplasm is more technically feasible since the early sixties, when UPOV was established (McConnell 2004). Furthermore, genotyping technologies are now available that can provide more than sufficient levels of detailed genotypic characterization for any conceivable breeding application. For example:

- sequence data can help identify useful genes,
- marker data can help select for heterosis,
- laboratory personnel have capabilities to generate data for thousands of markers per day,
- molecular marker data can also be created to unlock genetic potentials that currently reside in exotic, wild, or unadapted germplasm (Smith 2004).

Utility patents disclosing such breeding technologies would of course also benefit scientists in developing countries who could try and adapt such disclosed technologies for improving their indigenous crops.

However, on behalf of important representatives of the seed industry, primarily from the United States, Smith also expressed the following concern:

> These very technologies that can allow greater access to a broader base of genetics could instead, and far more easily, be used to speed and to facilitate a program that is designed to capture the key elite genetics from already existing and well-adapted varieties.

This concern is realistic, but should not be overrated. In particular, the bigger seed companies can use highly advanced breeding techniques. They also have stored in private databases an enormous amount of information about plant genomics, which potentially gives them a substantial technological advantage over smaller companies. Where classical breeding results, in general, in incremental improvements of a plant variety, the introduction of a valuable trait, by genetic engineering or otherwise, can result in a substantial value increase of several varieties. Such special traits, for example those encoding for insect resistance or herbicide tolerance, as well as the technology employed for the introduction of such traits can be protected by broad, strong, enforceable patents. The royalty income obtainable from special traits can accordingly be very important.

Of course, the strength and enforceability of patents depends on the claims granted, and there will always be countries where patents are not granted, not enforceable, or have not been filed. Patent managers daily confront the dilemma of whether to seek patent protection and publish or to keep a trade secret. Keeping an invention secret runs the risk of being blocked by a competitor's patent. So when considering the actual practice of utility patents for plant varieties, it would appear that often the aim is to protect both germplasm (preferably including progeny downstream of the F1) and trade secrets by not disclosing the breeding technology employed. In general, utility patents on plant varieties do not disclose the modern breeding techniques and markers used to developing them. But shouldn't they?

Disclosing such technologies would shift the emphasis from the innovator's rights to the public's benefits.

In this regard I tend to agree with Timothy Roberts that the balance should tilt towards the public good (27-28 May, 2004 Berlin). Innovators in the United States can choose to either meet the more stringent requirements of a utility patent (including satisfying the disclosure requirement) and get stronger intellectual property rights, or they can opt for the lower standards of the Plant Variety Protection system and obtain weaker rights.

4.3 Utility patents on plant varieties

Utility patents on plant varieties are rarely challenged. In all cases, a court action on fundamental issues would cost a fortune (easily tens of millions of dollars). This is particularly true for the United States and can be abused by bigger companies in legal disputes against small companies with limited financial resources. One should also bear in mind that in many complicated court proceedings the chances of success are around 50%, which implies that litigation is a high risk investment.

It is not surprising, therefore, that John H. Barton observed that "firms appear to be using their litigation budget primarily for disputes over fundamental patents, rather than for disputes over specific lines" (1988). Unless it is forced to do so to survive, a company will normally not start litigation to resolve basic issues about patenting plant varieties; the cost, uncertainty about the outcome, and the unforeseeable consequences for stakeholders are all factors that speak against opening this Pandora box.

One rare exception is J.E.M. Ag Supply v. Pioneer Hi-Bred. The issues decided upon by the US Supreme Court were fundamental, although it left many issues unresolved. Janis et al (2002), for example, observe that the Court did not comment on issues of patent scope, non-obviousness, enabling disclosure, enforcement of patents on plant-related inventions, patent infringement via pollen drift, infringement by plant breeding research by seed saving, and the enforceability of "seed-wrap" licenses. Other issues requiring further attention, though not necessarily court issues, are questions about novelty, progeny claims (F1 claims and progeny downstream of F1 progeny), the scope and enforceability of certain process claims, and Information Disclosure Statements (which must be filed for every patent application).

a. Novelty

According to UPOV, a plant variety "can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes." It is assumed that the USPTO employs in practice a definition for a plant variety that is substantially the same. A plant variety must have a unique combination of genes, a genotype. The genes are expressed and give the plant a phenotype. The phenotype of a plant varies depending on environmental conditions. It is accordingly necessary to do multiple side-by-side tests in different locations to establish with some degree of certainty if a plant variety is novel.

A main claim on a plant variety typically reads as follows:

- Inbred corn seed designated XXXX, having ATCC accession No. YYYYY

or

- A hybrid corn plant designated ZZZZ and its part, and having ATCC accession No. WWWWW.

ATCC stands for the American Type Culture Collection. It is one of the recognized culture collections in accordance with the Budapest Treaty. The United States is one of the countries allowing the deposit of biological material (e.g., seed) to assist patentees in describing their inventions in a reproducible way (see also "enabling disclosure" below).

The claim is based on a vague description in the specification of a phenotype, a unique combination of known traits (if one of the traits were novel, an inventor or patent attorney would aim for a generic claim). The overall improvement of the combination of traits is in general incremental and indefinable. If there is no relevant information about the prior art situation, no comparative field test data with the most relevant prior art, and if the most appropriate databases are unavailable or not consulted, then the task of a patent examiner is extremely difficult, if not impossible. This task is rendered even more complicated when one realizes that a phenotypic unique combination of traits will vary by environment. As Troyer explains (2002):

> Quantitative traits (cumulative action of many genes each producing a small effect) such as yield, grain moisture at harvest, stalk breaking, root lodging, ear dropping, and agronomic traits in general interact with environments (usually weather and cultural practices) that require many test locations to determine the relative value of a genotype.

Accordingly, the applicant for a patent must submit multiple data to illustrate the uniqueness of the particular variety. As regards patent examiners, it has recently been suggested that they need to use foreign databases more, including SINGER (the System-wide Information Network for Genetic Resources) used by the CGIAR, crop advisory committees, and the USDA/public sector "in order to reduce possible errors on improper patent grants for plant varieties" (see Farm Foundation 2003).

When enforcing a claim like "Inbred corn designated XXXX, having ATCC accession No. YYYYY" it is necessary to establish what the claim protects. Does it protect a phenotype or a genotype? If a phenotype is protected, which combination of traits is protected? The claims do not specify which unique combination of traits is claimed. Indeed, the phenotype is the expression of a genotype, and as stated before, such expression varies depending on the environment. The phenotypic difference between plant varieties is the result of a different impact of a particular combination of chromosome segments on the expression **level** of known traits in a particular environment. One might consequently take the position that it would be more appropriate to obtain protection for the genotype. However, if the genotype were protected, would a new variety distinguishable by marker analysis from a deposited, protected variety infringe, if the two varieties would appear to be phenotypically substantially similar?

b. Progeny Claims

A typical progeny claim reads as follows:

> A maize plant, or its parts, wherein at least one ancestor of said maize plant is the maize plant, or its parts, of claim x (note of author: see above hybrid claim), said maize plant capable of expressing a combination of at least 2 ZZZZ traits selected from the group consisting of:
>
> a. a relative maturity of approximately 117 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, (116; 15%)
>
> b. outstanding harvestable yield (9; 61%)
>
> c. excellent stalk lodging resistance (6; 32%)
>
> d. excellent root lodging resistance (8; 48%)
>
> e. good resistance to Common rust (6; 31%)
>
> f. good resistance to Stewart's Wilt (5; 68%)
>
> g. above average resistance to Gray Leaf Spot (5; 37%)
>
> h. above average resistance to Corn Lethal Necrosis (5; 41%)
>
> i. above average resistance to Southern Leaf Blight (5; 83%)
>
> j. above average test weight (6; 87%)

The first figure given for each trait is the relevant rating for the hybrid. It is followed by the percentage of entries in characteristics charts found in public Web Sites that meet or exceed the rating threshold inferred by these ratings for the traits in the patent.

Some key aspects of a progeny claim include:

- Its lack of uniqueness by finding two or three of the traits at the level disclosed in the patent. (Actually, it would be unique not to find two products that did not have common traits; the customer wouldn't want them if they didn't meet the market's needs.)
- The charts are regional charts for the simple reason that the traits of a given product can differ substantially across regions.
- Relative maturity is a unique situation because different markets desire and need different maturity. It is also a trait that is easy to manipulate.

Granted, the USPTO now tends to reject this type of progeny claim. Moreover, certain examiners investigate claims to F1 progeny more stringently, where the universe of progeny can be used as one parent and the deposited inbred line of claim X is the other parent. Such claims may be rejected because the genome is only approximately 50% described. It is difficult to understand how it can be reasonably assumed that generic claims for progeny downstream F1 progeny satisfy the novelty criterion.

c. Method claim

A typical method claim for plants developed using a deposited line in a breeding program reads as follows:

> A method for developing a soybean plant in a soybean breeding program comprising: obtaining the soybean plants, or its parts, of claim 2 and employing said plant or parts as a source of breeding material using plant breeding techniques.

Such claims, if valid, are suitable for infringement action against import into the United States of a novel plant variety derived from a plant variety patented in the United States and used in a breeding program outside the United States. The validity of such claims is believed to be questionable. The products formed by such a method claim are not described and include any and all products derivable from the patented and deposited variety, no matter how far downstream.

Although this is not an argument against the patentability of such method claims, one could wonder how far downstream one would have to go to be successful against an infringement attack. In addition, theoretically one could obtain the starting material used for development of the patented plant variety by reverse engineering. Such a generic claim would not be novel. Finally, it is also necessary to establish whether the product obtained according to the patented method or process had been materially changed by use of the breeding techniques, and if so whether the exemption according to Section 271 (g) would apply. This exemption states:

> A product which is made by a patented process will, for purposes of this title, not be considered to be made so after … (3) it is materially changed by subsequent processes…

If the new variety could be protected by utility patent—implying that it was unobvious from the starting material—would it be an argument for material change of the variety used as starting material?

d. Information Disclosure Statements

The inventor has the duty to disclose pertinent prior art to the examiner. It would appear that this duty is not very diligently followed for plant varieties.

e. Unobviousness

This section is about utility patents for plant varieties—not about patenting novel traits. For the latter, one logically aims for generic claims; these are broader in scope and easier to enforce. Patent specifications on plant varieties are for a combination of known traits. Such combinations, however, often risk a lack of novelty; the difference may be so incremental that the best way to document potential unobviousness is to submit many data. Probably the only hypothetical way to accurately define a variety would be to identify the set of genes or chromosome segments responsible for the particular expression of a given agronomic trait.

One way for examiners to solve the problem of obviousness is to decide that every novel plant variety is in principle unobvious. Indeed, strictly speaking, it is even a surprise to the breeder that s/he obtained exactly that particular variety. Is every novel plant variety *ipso facto* also unobvious? In such case the novelty/unobviousness criterion applied for utility patents on plant varieties would be essentially equivalent with the distinctness criterion according to UPOV. This was not the understanding of the Court:

> The requirements for obtaining utility patent under §101 are more stringent than those for obtaining a PVP certificate, and the protections afforded by a utility patent are greater than those afforded by a PVP certificate. Thus, there is a parallel relationship between the obligations and the level of protection under each statute. (S.C. on J.E.M. AG Supply, Inc., v. Pioneer Hi-Bred International, Inc.)

However, the reality is that the novelty/unobviousness requirements for obtaining utility patents on plant varieties as applied by the USPTO are indeed substantially the same, if not less stringent than the distinctness requirement applied by the US plant Variety Protection Office (USPVPO). It is believed the Court indicated what the practice ought to be, not what it is. See for example The Crucible II Group 2002:

> In principle, the process and result are often obvious, though they may take years of expensive and painstaking work. In such cases, a Patent office may reasonably reject a patent application for lack of inventiveness.

The author's experience with the Japanese Patent Office's (JPO) examination practice of patent applications for plant varieties, which is admittedly limited, appears to indicate that the JPO's examination standards for inventiveness regarding plant varieties are substantially higher than those of the USPTO.

f. Enabling disclosure

WIPO's *Guide to the Deposit of Microorganisms under the Budapest Treaty* describes the current guidelines for disclosure as follows:

> A fundamental requirement of patent law is that the details of an invention must be fully disclosed to the public. For disclosure to be adequate, an invention must be described in sufficient detail to permit a person skilled in the art to repeat the effect of the invention: in other words, the disclosure should enable the average expert with access to the appropriate facilities to reproduce the invention for himself.…Inventions involving the use of new microorganisms (i.e. those not available to the public) present problems of disclosure in that the repeatability often cannot be ensured by means of a written description alone….This line of reasoning led to the industrial property offices in an increasing number of countries either requiring or recommending that the written disclosure of an invention involving the use of a new microorganism be supplemented by the deposit of the microorganism in a recognized collection. The culture collection would then make the microorganism available to the public at the appropriate point in the patenting procedure."

The statement made herein with respect to microorganisms also applies *mutatis mutandis* to seed. In the document WIPO/GRTKF/IC/5/10.103 it is emphasized that "the deposit of a microorganism or other biological material does not relieve the patent applicant of the obligation to provide as full a written disclosure as possible." This statement is in line with the PTO's requirements for applicants to describe deposits as set forth in 37 C.F.R. § 1.809(d), which states,

> For each deposit made pursuant to these regulations, the specification shall contain:…(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination….

But utility patents for plant varieties rarely disclose the breeding strategy, much less the markers used in such a breeding strategy. As Smith (2004) observes, "pedigree data do not provide much, if any information to help anyone to develop an improved variety". Pedigree data without detailed information about the markers employed for the breeding strategy would accordingly have little or no value from a disclosure viewpoint.

5. Conclusion

In the light of the above it would appear that properly examining most patent applications for plant varieties is nearly impossible and that the validity—and therefore the enforceability—of utility patents on plant varieties is not beyond question.

Despite the many issues that remain unresolved concerning utility patents for plant varieties, companies have no choice realistically but to seek protection for a novel plant variety via utility patents and PVP; this is particularly true for field crops. Companies must seek patent protection if, for example, they want to have a bargaining chip against a competitor to access his germplasm for breeding purposes. They must seek a plant variety certificate if they want to be sure to have protection that is substantially more likely to survive litigation and that may effectively have even a somewhat broader scope of protection (because of the concept of essential derivation) than that of a utility patent on the same plant variety, which offers (theoretically) weaker protection because of the breeders' exemption. The farmers' exemption in the US must not be a problem; this depends more on the political will to adjust the PVPA in respect to the utility patent.

It would appear there is an urgent need for guidance from the USPTO in many aspects, maybe in the form of special guidelines for examination of patent applications on plant varieties under the 35 U.S.C. written description requirement.

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An Overview of Plant Variety Protection in South Africa [1]

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Executive Summary

We provide an overview of mechanisms through which plant varieties can be protected in South Africa, discuss the national economic and regulatory environment in which plant breeders operate, and illustrate the benefits and deficiencies of the plant variety protection system in South Africa.

South Africa has a well-diversified economy and an agricultural regulatory system that aims at safeguarding production efficiency, based on access to quality plant genetic resources. Plant breeding is regulated under several legislative regimes that create a reasonably favorable environment for research and development. Plant variety protection is available under Plant Breeders' Rights, trade marks, and patent rights for genetic modification technologies that exclude patentability on the variety itself. Protection can also be managed under licensing and contractual agreements. Since South Africa became the 10th member of UPOV in 1978, applications for breeders' rights steadily increased to reach 1646 protected varieties, some 42 per cent of which is owned by local breeders.

Ongoing introduction of new, improved varieties has played a key role in supporting agricultural production efficiency. Public and private breeders have made extensive use of local and international germplasm for direct commercial introduction or for further breeding to achieve local adaptation. Plant variety protection has been one factor in facilitating such access and investment in breeding by the private sector, including entrance by small companies.

Since Plant Breeders' Rights intrinsically do not provide very strong protection of ownership, breeders have applied several options to safeguard their interests. Some have focused on hybrids, while others have used mandatory seed certification, licensing and contractual agreements, or employing an independent party to police infringements. Modern GM crops also make use of patents and trade marks.

Plant variety protection has stimulated introduction of foreign bred varieties, as well as local breeding, as can be seen from the present range available to farmers and from the ongoing release of new varieties. Commercial and small-scale farmers have increased production efficiency as result of new, improved varieties. However, threats and constraints include the historic problem of farm-saved seed for which no agreement has yet been reached between farmers and breeders. New biodiversity legislation and amendments to existing patent regulations may complicate rather than facilitate investment in beneficiating the rich biodiversity in the country. The absence of active participation of plant breeders individually and collectively through their Southern African Plant Breeders' Association, remains a cause for concern.

1. Introduction

South Africa presently ranks amongst the top group of emerging economies with a GDP of ZAR1.2 trillion (US$200 billion; STATISTICS 2004). This is twice as big as the second biggest economic power in Africa, namely Egypt. Its agricultural sector has been the mainstay of the economy until mining took the lead in the early 20th century, followed by industrial production since the 1950s. The country, however, has continued to be a net food producer as is evident from the 2002 agricultural statistics (Department of Agriculture 2004a) that show agricultural exports worth $4,4 billion, comprising $2.7 processed products and $1.7 billion unprocessed products, against imports of $2.4 billion. Agriculture makes up 8.9% of a total of $50 billion exports. Imports of agricultural products comprise 5.4% of the total of $44 billion. Although agriculture now makes up less than 4% of the economy, it employs 15% of workers in the formal sector, and its forward and backward linkages account for an estimated 15% of the economy. Its real value, however, should be seen in the context of providing ongoing national food security and affordability.

The history of agriculture is intertwined with the history of the plant and seed industries. A range of European varieties accompanied the first settlers in 1652 whose primary initial mission was to establish

food production to serve passing ships, while indigenous tribes made use of extensive biodiversity for food and medicine. The first private seed companies were established in the 1890s and the first private seed testing laboratory was established in the 1940s, coinciding with the founding of the official government seed testing station. Official public maize breeding dates back to 1903 while hybrid maize breeding commenced in 1948 under guidance of three American scientists: Josephson, Grogan and Jenkins (Kühn and du Plessis 1994). Progress in crop production efficiency took a leap with introduction of hybrid maize, new varieties of many other species, and increased use of fertilizers and crop protection chemicals. Average yields per hectare for maize increased five-fold from 1950 to 1999, and four-and-half-fold for wheat in the same period (Van der Walt 1999). South African companies and breeders benefited in various ways from access to global germplasm: new varieties for direct commercial use, varieties that had to be re-selected and cross-bred for local adaptation, and inbred lines for use in hybrid combinations. Naturally, extensive use was also made of germplasm in the local domain.

Organization of the plant and seed industries started at an early stage with establishment of a nurserymen's association around 1915, the Seedsmen's Association of South Africa in 1942, the South African Hybrid Seed Producers organization in 1959, the Plant Breeders Association in 1966, the South African Forage Seed Association in 1981, and the Association for Seed Analysts also in 1981. In 1989 the various seed associations were merged into a single representative body, the South African National Seed Organization (SANSOR), and a secretariat with offices was established (Van der Walt 2002a). Presently SANSOR has over 100 members representing the biggest national seed market in Africa with annual turnover of $220 million (Loubser 2004).

2. Seed and Plant Regulation

Legislation pertaining to seed and plant species is intended to facilitate ongoing availability of quality plant genetic resources to support production efficiency in agriculture, an orderly industry and a conducive environment for research and development.

The Plant Improvement Act (Act 53 of 1976, as amended) regulates trade in seed and plants, variety lists, voluntary certification of seed quality, and seed quality testing.

Seed and plant species are regulated in several ways: some species are unregulated as long as the label showing the variety name and information is truthful, some species with no official variety lists, and major species with compulsory variety listing based on tests for novelty, distinctiveness, uniformity and stability.

The Plant Pests Act (Act 36 of 1983, as amended) deals with plant health issues such as phytosanitary certificates and quarantine pests.

The Plant Breeders' Rights Act (Act 15 of 1976, as amended) provides for breeders' rights under the UPOV Convention. South Africa upgraded its 1961 breeders' rights legislation and became the 10th member of UPOV in 1978. The Act was amended in 1996 to meet UPOV 1991 requirements, except for extending eligibility to all plant species, but the country has not yet acceded to UPOV 1991. The Registrar of Plant Breeders' Rights maintains a list of species eligible for breeders' rights.

The Genetically Modified Organisms Act (Act 15 of 1997) regulates all genetic modification (as defined) of all organisms, as well as all activities relating to GMO work from academic research to contained use, trial release, seed and plant production, commercial release, imports, exports, farm management practices, to commodity trade. Decision making is vested in one body, The GMO Executive Council, comprising senior officials from 6 government departments.

The National Environmental Management Biodiversity Act (Act 10 of 2004) regulates, amongst other things, the exploitation of indigenous biological resources. Plant material is included in the definition of genetic resources.

The Patents Act (Act 57 of 1978) provides for the patenting of new and inventive inventions which can be used in trade, industry or agriculture. It does, however, exclude the patenting of varieties of plants and animals or natural biological processes.

The Trade Marks Act (Act 194 of 1993) allows for trade marks to be registered which are capable of distinguishing the goods or services of a person from the goods or services of another person.

3. Status of Plant Variety Protection

The official variety lists (Department of Agriculture 2004b) show 215 varieties of 28 forage and pasture species, all open-pollinated; 918 varieties of 21 species of winter and summer grain, oil and protein, and industrial crops of which 439 are open-pollinated and 479 hybrid; 871 varieties of 18 vegetable species comprising 267 open-pollinated and 604 hybrids. Apart from these 2004 varieties, there are 27 forage species, 2 field crop species, 12 vegetable species, as well as ornamental and fruit species for which no official lists are required. This makes an estimate of between 3500 and 4000 varieties available to farmers and gardeners, taking into account that the availability of 1646 of these varieties is subject to plant breeders' rights.

Plant Breeders' Rights legislation was drafted in 1961 and updated in 1976 to meet UPOV 1978 requirements. The country became the 10th member of UPOV in 1978. In 1996 the Plant Breeders' Rights Act was amended to meet UPOV 1991 requirements. Breeders' rights applications grew steadily and stabilized at just over 1600 rights awarded. The status in 2002 stood at 1603 rights in force, comprising 618 ornamental varieties, 223 fruit, 234 vegetable, 384 agronomic field crops, and 144 forage and pasture. Nationality of breeders was 669 varieties owned by South Africans (42 per cent of total), 219 owned by Americans, 195 by Dutch, 129 by Germans, 117 by French, and the balance spread amongst breeders in more than 10 other countries (Van der Walt 2002b). At the end of 2003 the total number of rights in force amounted to 1646 (Department of Agriculture 2004c). By plant group these comprised 346 agronomic field crop varieties, 36 industrial, 220 fruit, 678 ornamentals, and 227 vegetable varieties (Van der Walt 2004).

3.1 The role of trade marks in respect of plant variety protection

A trade mark for a plant variety may be registered under the Trade Marks Act provided it complies with the normal requirements for trade mark registration. In terms of both the Trade Marks Act and the Plant Breeders' Rights Act it is not possible to register the actual denomination of a plant variety as a trade mark. Like in other parts of the world it has become popular in South Africa to brand the fruit of a new fruit variety under its own unique trade mark. In doing so the owner builds up a reputation in the trade mark. This approach has the further advantage that at the end of the Plant Breeders' Right protection period the owner of the fruit variety is in a position to demand a royalty payment for the use of the trade mark when third parties want to sell fruit of the plant variety under the trade mark.

There are now examples of trade marks being used in respect of the fruit of plant varieties originating from South Africa. An example is the trade mark AFRICAN PRIDE being used in relation to yellow plums.

3.2 Patents on plants

The previous Patents Act (the 1915 Act) made provision for patenting of plant varieties but this was probably never used. When the existing Patents Act was adopted in 1979 the provision was removed as South Africa then had in place the Plant Breeders' Rights Act. The existing Patents Act specifically excludes the patenting of varieties of plants and animals or natural biological processes. The relevant section of the Patents Act provides that; "A patent shall not be granted for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process." A micro-biological process or the product of such a process is, therefore, not subject to this exclusion on patentability. It is possible, therefore, to patent a micro-biological process relating to, for example, creating a genetically modified plant variety. The product of the micro-biological process i.e. the plant itself is also protectable by a patent. Although this provision under the Patents Act has not been used often it is believed that it may become more relevant as and when genetically modified plant varieties become more acceptable as a source of food. At the same time it will be possible to protect the plant variety obtained through a micro-biological process also under the Plant Breeders' Rights Act.

It is important to remember that new patent applications in South Africa are only examined as to formalities. No substantive examination is undertaken. The onus is on a third party who wants to challenge the patent to show that the patent is invalid.

It often happens that South African patents are filed with wide claims. A South African patent can be amended any time during its lifespan and it is therefore common to amend the claims of a South African patent to bring them in line with the claims granted in foreign jurisdictions, where the corresponding patent has been examined. This system has worked well for South Africa and there are no plans to change the South African patent system to a system where substantive examinations are conducted.

3.3 The Biodiversity Act

This is a new piece of legislation. It finds its roots in the Convention on Biodiversity of which South Africa is a signatory. In terms of the Biodiversity Act a person will require a permit to use (exploit) indigenous plant material. It will further be a requirement to have a benefit sharing arrangement in place with the community from which the indigenous plant material originates. The practical implementation of the Biodiversity Act may turn out to be problematic. A number of the provisions of the Biodiversity Act will only come into force in 2005 and in 2006. Regulations for the Biodiversity Act have not been published as yet. The concept of "farmers' rights" protection for traditional selections and landraces has been debated at length but no guidelines or draft regulations have yet seen the light, other than general provisions in the above Act.

3.4 Protecting new plant varieties by way of contract

New plant varieties can also be protected by way of contract law. This is particularly the case in respect of asexually propagated plant varieties. The owner of a new plant variety also owns the plant material. If plant material is never sold to third parties then nobody can claim to have a legitimate source of the plant material. The owner, however, can allow third parties to grow the plants under contract, while retaining the ownership in the actual plants. This system has been referred to as the personal property theory in relation to plant varieties. Although it has not been tested in our courts one cannot fault the personal property theory on basic legal principles. There are presently licence agreements in place in South Africa in which the owner of the plant variety retains the ownership of the actual plants grown by the licensee. The licensee must then pay a royalty to the owner on the products produced from the plants. As long as the licensee pays its royalties and complies with the other terms and conditions of the licence agreement then the owner has no say over how the licensee has to deal with the plants in issue.

However, when the licence agreement is cancelled then the licensee must destroy all the plants or hand them back to the owner.

Owners of new plant varieties normally spend a substantial amount of time and money in generating new plant varieties. They, therefore, realize that it is important to protect their Intellectual Property relating to new plant varieties. In doing so, it is often appropriate to use a combination of protection mechanisms.

4. Strengthening PVP in South Africa

Plant Breeders' Rights under the UPOV Convention inherently do not provide the same strength of protection as can be obtained under patents or trade marks. Firstly, in most countries infringement of such rights is not regarded in the same light as contraband or counterfeit of trade mark or patented goods. All IP rights must be defended under the civil law by the owner of such rights.

Secondly, strong protection is somewhat weakened by exemptions for research purposes, further breeding and private use. It is weakened more by Article 15(2) of UPOV 1991 that allows use by farmers of farm-saved propagating material for re-planting and where the qualification "subject to the safeguarding of the legitimate interests of the breeder" is not defined. In 1996 South African law makers used this exemption to insert an ambiguous paragraph in the amendment to the Plant Breeders' Rights Act that states that the rights shall not be infringed "if the person is a farmer who on land occupied by him or her uses harvested material obtained from that propagating material for propagation, provided that harvested material obtained from the re-planted propagating material shall not be used for purposes of propagation by any person other than the farmer". The word "re-planted" actually deletes protection of the first generation of harvested material.

Thirdly, the concept of "essentially derived varieties" in Article 14(2)5 of UPOV 1991 establishes the EDV principle but does not provide clarity on criteria that will constitute infringement. This provision is incorporated in the South African legislation.

Fourthly, South Africa has had only a few cases of infringement of breeders' rights and most disputes have been settled out of court. The only known cases over a 26 year period involved Sugraone table grapes, a potato variety, a rose, a canna, a strawberry, a calla (*Zantedeshia),* and a pepper variety. The latter case has not yet been declared a formal dispute. Therefore, we have not had adequate litigation to provide well-publicized watershed cases.

In the light of the above legal environment, South African breeders and licensees have followed different routes to protect their interests.

1. Although plant breeders' rights have spurred private investment in breeding open-pollinated and self-pollinated crops, a significant shift towards hybrids manifested itself where genetically possible. Very few new open-pollinated varieties of maize, sorghum, sunflower and sweet corn have been bred. Some 69 per cent of all 871 vegetable varieties listed are F1 hybrids. Vegetable hybrids have shown, despite the increased seed cost, that farmers benefit from improved traits such as pest and disease resistance, increased yield potential, appearance and quality to meet local and export market preferences. For seed companies benefits lie in higher seed prices and margins, and in farmers not retaining seed from harvested products. However, comparative socio-economic impact studies with open-pollinated varieties and hybrids in South Africa by independent parties have not yet been done.
2. Official seed certification is intended to preserve high quality standards, specifically genetic trueness-to-type. It is not intended to strengthen ownership. However, a breeder may request that only certified seed of his variety may be sold and such certification recognizes only the breeder as source

of authentic breeder seed, and sale of uncertified seed without approval amounts to violation of the Plant Improvement Act. Indirectly this strengthens ownership.

3. A system for licensing public varieties bred by the Agricultural Research Council (ARC) ensures maintenance of quality standards and formalizes commercial marketing, while providing an opportunity for collecting royalty fees for the institute concerned. All new public varieties enjoy plant breeders' rights protection and are marketed under licence agreements. In the case of seed crops this is handled by the South African National Seed Organization. (SANSOR). Licences are awarded through a consultative process involving the ARC institutes, SANSOR and the seed industry members. Licences are designed for handling seed for research purposes or evaluation before licensing. Licences may be awarded for varieties or inbreds to be used in hybrids for commercial sales, and may involve one applicant for exclusive use, a consortium of applicants or general use by all qualified seed enterprises. Seed trade members are advised beforehand of release of a new variety and conditions for application: open to all or exclusive on the basis of a tendering procedure.
4. Many seed companies have adopted the recommendation that varieties protected under plant breeders' rights be identified in their marketing brochures and in sales documentation with wording to the effect that unauthorized propagation and marketing are a punishable offence.
5. Quite a number of ornamental varieties are being protected under a trade mark name and labels will indicate that unauthorized propagation is an offence.
6. In view of abuse of the "farmers privilege" by some and the opportunity for violating licensing contracts, SANSOR and its members in 2003 embarked on contracting Agri-Inspec, a private industry organization involved in monitoring contraband and irregularities in agricultural commodity trade on behalf of agricultural industry sectors. Minor offenses, especially by farmers, are dealt with on a first warning basis, whereas serious infringements and repeated offences are dealt with through litigation or by settlement out of court. During 2003 five court cases led to fines for the infringers. This action is backed up by regular awareness campaigns conducted via the media (Hanekom 2004).
7. Genetically modified varieties (GM) are usually protected under a patent on the genetic construct and claims associated with the modification, a trade mark on the name, and often a plant breeders' right. Typical trade mark names include NuCoTN®, RoundupReady®, Yieldgard®, INGARD®, and Bollgard®. In many conventional and GM varieties the trade mark company name is used as a prefix to the variety name or number. Sales of GM seed are often accompanied by a contract stipulating that the farmer shall not retain seed for propagation or selling purposes. This is considered necessary in order to protect ownership, to ensure that genetic integrity of the variety is maintained as admixed seed cannot be properly managed in terms of herbicide and insecticide practices, to enable the seed seller to keep government informed of who is planting GM crops, and to ensure the practice of identity preservation of products derived from the crops.
8. Many breeders of ornamental and fruit tree varieties make extensive use of contractual agreements for production and marketing of products. One other interesting case in point is the South African Sugar Association (SASA), established in 1925, that has as one their major functions the breeding of new varieties at their South African Sugar Research Institute (formerly known as SASEX). Their very successful track record includes the fact that an estimated 90 per cent of all cane sugar presently produced in Africa, is based on South African bred varieties. The variety NCO310, released in 1945, was made available to some 50 countries and became the most widely grown variety in the 1960s (Van der Walt 1994). It is SASA policy not to take out plant breeders' rights as funding is derived from a levy from the sugar industry and new varieties are made available freely to all local cane growers. However, use of these varieties in other countries is managed by way of agreements with research institutions and countries, negotiated on a case-by-case basis, and may involve payment of royalties. Nevertheless, patent rights are taken out on claims associated with modern biotechnology such as gene constructs (C Baker 2005; pers. comm.).

5. Benefits of PVP

It remains difficult to quantify the benefits arising from plant variety protection systems as there is not a comparative system without variety protection. However, one could compare the present availability in South Africa of new local varieties and access to international varieties with the situation before breeders' protection and also with countries where no protection exists. It then becomes clear that it has been a win-win situation for farmers, breeders, agricultural production efficiency, and economic benefits. The following benefits can be highlighted:

- The ongoing increase in applications for Plant Breeders' Rights shows that breeders attach value to protection systems.
- Plant Breeders' Rights add peace of mind to buyers in that the varieties meet standards of trueness-to-type and to breeders that the risk of piracy is minimized.
- Although not many breeders take out Plant Breeders' Rights on parental inbred lines, access to such local and international germplasm has played a key role in hybrid development
- Likewise, access to protected international varieties for direct commercial use and for further breeding under licensing and contractual agreements, has laid the foundation for global competitiveness in fruit exports. Locally bred varieties make up 58 per cent of peach, 30 per cent of table grape, 23 per cent of nectarine, 3 per cent of pear, 10 per cent of apricot, and 80 per cent of plum exports. Improved varieties have also been important in making South Africa the 13th biggest producer and 3rd biggest exporter of citrus fruit in the world (Van der Walt 2002b). Virtually all groundnut, wheat, rye, oats, barley, and dry bean varieties used domestically are locally bred and most of these enjoy Plant Breeders' Rights.
- A growing number of one-man and small company breeding operations, including farmers, have obtained breeders' rights on their selections and, especially, on new varieties and hybrids of indigenous flowers.
- The private sector has become more involved in breeding "orphan crops", i.e. self-pollinated and open-pollinated minor species.
- All new public varieties bred by institutes of the Agricultural Research Council enjoy breeders' rights locally and the ARC has been able to obtain Plant Breeders' Rights for its varieties in foreign countries, enabling it to license its varieties to interested parties. This has led to the potential for generating substantial income for the country, now that it has become common to also demand a royalty on the fruit of, specifically, fruit varieties. It is interesting that the drive to have varieties of seed crops licensed through SANSOR came from a farmers association. The justification was that new public varieties were made available too slowly and that no seed merchant was spending money on promoting the varieties as there were no exclusive licences. Often seed quality suffered. The ARC licenses fruit tree and ornamental varieties locally and internationally through various other parties.
- Enforcing ownership of protected seed varieties through an agreement with AgriInspect appears to have reduced alienation of seed crop varieties.
- Intellectual property rights and contractual agreements are alleged by some as creating monopolies to the exclusion of and detriment to resource-poor small-scale farmers. Telephonic interviews with various seed and plant enterprises revealed that this allegation is not substantiated. Three crop species cases highlight the benefits to small-scale farmers:

  (a) GM cotton: Small-scale farmers had difficulty in growing cotton economically due to low world prices and losses caused by bollworm. An integrated approach combining new Bt varieties, extension services, credit facilities and access to a cotton buyer, resulted in rapid adoption that reached over 90 per cent within five years and involving over 3000 farmers. An independent impact analysis proved the socio-economic benefits (Ismaël *et al.* 2001). However, a seed company spokesperson emphasized that it is company policy that no GM cotton varieties will be made available to countries

that do not have intellectual property protection systems and biosafety regulations in place. Countries that do not provide such protection, in fact, deprive their farmers of the opportunity to benefit from improved technologies (Olivier 2005; pers. comm.).

(b) Vegetable varieties: Seed suppliers have accepted that resource-poor farmers tend to retain seed of open-pollinated varieties for re-use and there has never been a single case where any company has taken action against such farmers. However, companies will take action against large-scale commercial farmers who save seed of proprietary protected varieties and sell it on the market. Small-scale farmers who also market all or part of their crop commercially have exhibited a strong trend towards using more expensive hybrid seed as result of benefits derived from improved yields, disease resistance and product qualities (M Sachs 2005, pers. comm.; HB Roode 2005, pers. comm.).

(c) Sugar cane: The South African Sugar Association started to develop new small-scale farmers some 25 years ago and presently this category has grown to over 50 000 farmers. They enjoy the same free access to new varieties and marketing assistance as commercial farmers. In this case varieties do not enjoy plant breeders' rights protection as result of industry policy. Small-scale farmers in the rest of the world also have access to these varieties as result of contractual agreements. South African varieties underpin sugar cane production in Africa (C. Baker 2005; pers. com.)

- The key issue is that successful crop production efficiency in serving domestic and export markets depends upon ongoing availability of improved varieties and such availability is evident from the numbers of new varieties entering the market every year. International seed and plant companies have expressed a clear strategy: they will not introduce new varieties in a country that does not have adequate plant variety protection systems.

6. Threats and Impediments

Despite an enabling South African environment for plant breeders, several threats and impediments continue to exist. These include the following:

- Farmers enjoy no government support in terms of subsidies and need to survive in a highly competitive global market. The practice of farm-saved seed continues especially in self-pollinated crops with low profit margins such as winter cereals, soybeans, and groundnuts. There is presently no agreement between seed companies and farmers on a royalty system for such farm seed.
- The Plant Breeders Rights Act, amended in 1996, meets UPOV 91 requirements except for eligibility of all species. This causes a delay in getting new species included on the list of protectable species maintained by the Registrar of Plant Breeders' Rights.
- It is government policy to encourage public-private research partnerships but the key issue of joint intellectual ownership and benefit sharing has not been clarified in practice. The Government has indicated, however, that it is working on a formal Intellectual Property Policy.
- The new Biodiversity Act embodies noble objectives in meeting the requirements of the Convention on Biological Diversity, as well as protecting and beneficiating our rich heritage of over 20 000 indigenous plant species. However, the Act is complex, bureaucratic and difficult to implement and may impede rather than facilitate plant breeding and intellectual property rights on indigenous species. The definitions of "indigenous biological resources", "indigenous species", "introduction", and the Article 80(b) dealing with bioprospecting contain ambiguous wording. The latter Article extends the scope of legislation to "any variety, hybrid or derivative originating from indigenous resources". This could imply special permits and certain limitations on breeding from thousands of varieties in the international commercial domain that have originated from local germplasm such as gladioli, gerbera, calla, protea, geranium, and scores of other species. Such impediment may be in conflict with breeders' privilege under UPOV.

- South Africa is in the process of harmonizing its various intellectual property rights systems. One recent outflow was a proposed insertion in the Patent Amendment Bill 2004 in Article 25(A) that provides for "… non-disclosure or wrongful disclosure of use of prior or indigenous knowledge, oral or otherwise, as grounds for rejection or revocation of an application" (25(A)1) and "any interested persons may institute legal actions with a view of rescinding the patent" (25(A)4). The first provision can be supported on moral grounds but there is presently no system for protecting prior or indigenous knowledge that could underpin practical implementation of the amendment. WIPO is still at an early stage in developing global guidelines for handling this issue (WIPO 2004). The second amendment could be supported on constitutional grounds relating to transparency and democracy but history has taught us that such provision is being abused by a global activist network to institute expensive litigation and delays on frivolous grounds.
- South Africa has been following the process at the WIPO Intergovernmental Committee on Intellectual Property, Traditional Knowledge, Genetic Resources and Folklore. South Africa will also no doubt follow the present initiatives at the WIPO to consider disclosure requirements relating to Genetic Resources in patent applications. Hopefully future proposed amendments to the South African Patents Act will take into account the developments and proposals which have emanated from the processes followed at the WIPO.
- Various industry bodies have been making inputs into new legislation or legislative amendments but their efficacy could be questioned as little lobbying with law makers seems to exist. Moreover, the Southern African Plant Breeders Association, established in 1966 and having extended their membership to almost 200 regionally, has to date not issued a single position statement on issues affecting them. Neither have they made direct inputs into legislation or lobbied government. They continue to miss opportunities to act as spokesbody on plant variety protection issues.
- The South African Patent Office is not yet computerized. Therefore, it is still necessary to conduct subject matter searches. The records, however, are presently being scanned and it may become easier in the future to search through patents filed at the South African Patent Office. Normally for any important South African patent there exists a counterpart in a foreign country or countries. It is, as a general rule, easier to check on the patent family of a foreign patent to establish if a corresponding South African patent was filed.

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