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ANALYSIS AND OPPORTUNITIES OF INTELLECTUAL PROPERTY PROTECTION FOR PLANT SCIENCE INVENTIONS APPLIED TO THE SEED INDUSTRY

ANÁLISE E OPORTUNIDADES DE PROTEÇÃO DE PROPRIEDADE INTELECTUAL PARA INVENÇÕES NA CIÊNCIA DE PLANTAS APLICADA NA INDÚSTRIA DE SEMENTES

Markus Richard Ritter

Abstract: Granting patents on inventions related to life has been controversial since the first patent laws were drafted. However, the need to recognize intellectual property on the work done by plant breeders started to emerge around 1900. In the 19th century plant breeding was largely done by public institutions. The concept of hybrid breeding started with corn around 1825, but it took another century until the first commercial release of corn hybrids. Plant breeders recognized early on two main advantages of hybrid crops over variety crops, namely the benefits of heterosis (e.g. higher yields) and the biological means to protect their work and to prevent farmers making copies of their breeding work. In 1930 the US parliament approved the Plant Patent Act, the first law of this type. In Europe discussions about plant variety protection started in 1911. However, it took several conferences during half a century until in 1961 the first international convention on plant variety protection was created. In 1994 within the GATT negotiations the TRIPS agreement was signed. The TRIPS

agreement requires member countries to establish patent laws and also defines the minimum requirements and permissible exceptions related to inventions dealing with living subject matter. Patents and plant protection laws motivated private investments and as a result the seed business has almost entirely changed from the public to the private sector. The development of modern biotechnology from the 1980s on once more caused law makers to review patent concepts on inventions no longer related to entire plants but now to specific cell functions and cell expressions which can be transferred by using transgenic technology between different species. While US patent office grants utility patents relatively generously, the Brazilian patent office INPI appears to be stricter in recognizing novelty in an invention, in particular for those created through induced mutagenesis, or applications are simply rejected on the basis of the Articles 10 and 18 of the Brazilian patent law (L9279/96).

Keywords: Patents. Mutagenic Plants. Transgenic Plants. Rice Hybrids.

Resumo: A concessão de patentes para invenções relacionadas a seres vivos foi sempre um tema controverso desde a implementação das primeiras leis de patentes. A necessidade de reconhecimento da propriedade intelectual para o trabalho feito pelos melhoristas (*plant breeders*) começou a surgir por volta de 1900. No século 19 o melhoramento de plantas era feito primordialmente por instituições de caráter publico. Os conceitos de criação de híbridos começaram a surgir com o milho por volta de 1825, porém demorou mais um século até os primeiros lançamentos comerciais no mercado. Melhoristas reconheceram rapidamente duas principais vantagens do conceito de hibrido. Primeiramente o beneficio da heterose (p.ex. maior produtividade) e um meio biológico de proteção da suas criações para prevenir os agricultores de fazer uso de semente própria. Em 1930, o parlamento americano aprovou a Lei de Patentes para Plantas, a primeira lei dessa natureza. Já na Europa, debates sobre a proteção da variedade de plantas começaram em 1911, porém foram necessárias muitas outras reuniões e mais meio século até a aprovação em 1961

da primeira convenção de proteção de variedades de plantas. Em 1994, dentro das negociações de GATT o acordo TRIPS foi firmado. O acordo TRIPS estabeleceu para os países signatários a necessidade de estabelecer leis de patentes e definiu os requisitos mínimos e as exclusões permitidas relacionados à matéria de seres vivos. Patentes e leis de proteção de plantas motivaram o investimento de recursos privados e, como resultado, o negócio de sementes mudou quase por completo do setor público para o setor privado. O desenvolvimento da biotecnologia moderna a partir de 1980 mais uma vez forçou os legisladores a revisar os conceitos de patentes já que as invenções agora não estavam mais ligadas a uma só variedade, mas a funções específicas de células as quais, com ajuda da transgenia, podiam ser transferidas de uma espécie para outra. As autoridades americanas de patentes têm outorgado patentes de utilidade com certa generosidade. Já no Brasil o INPI tem adotado uma política mais restrita no reconhecimento do caráter de novidade da invenção, em particular quando se trata de invenções obtidas através da metagênese induzida. A concessão também é negada às vezes com base nos artigos 10 e 18 da Lei nº 9.279/96.

Palavras-chave: Patentes. Plantas Mutagênicas. Plantas Transgênicas. Arroz Hibrido.

Summary: 1. Introduction. 2. The Case. 2.1 Patent infringement and royalty collection — Roundup Ready Soybean. 2.2 Royalty collection on mutagenic Clearfield Rice technology. 3. The convergence of plant breeding and intellectual property. 3.1 Patents in Plants. 3.2 The TRIPs Agreement and its application in national legislations. 3.3 Patent Law for Micro-Organism. 3.4 The Scope of plant breeders rights according to UPOV-style PVP. 4. Utility Patents in the USA. 5. European Legislation and Cases on Patents on Plants. 6. Important differences between Patents (US) and PVP (UPOV) for cultivar protection. 7. Patent limitations on biotechnological inventions, a comparison between Brazil, the European Union and the USA. 8. Patents on biological processes. 9. Patent Protection for Haploid Plants. 10. Patent applications related to plant related mutagenic inventions. 11. Conclusions.

1. Introduction

This paper is written from a practical standpoint of an agribusiness manager confronted with questions related to intellectual property rights in the field of biotechnology. The author is the managing director of RiceTecs South American affiliates, a company dedicated to research, development and marketing of hybrid rice seed and associated technologies.

A comparison of the patent laws will also be made to understand what the legal differences are in the granting or rejection of a patent for the same invention in the USA and in Brazil and how these questions are treated in Europe. The paper also analyses the historical development of plant related intellectual property laws and how these impacted a shift from public to private research and development.

The application of modern breeding and biotechnology in food crops has rapidly grown over the last hundred years. For centuries farmers have engaged in pre-scientific empirical crop improvement mainly through selection of plants with favorable characteristics. Evidence of more systematic and scientific approaches to crop improvement started in Europe in the 17th century. There are a number of interesting discoveries in plant science in the 17th and 18th century just to mention a few remarkable milestones forming part of our agribusiness tradition as well summarized by DENIS MURPHY[1]. By the end of the 17th century the German scientist Rudolph Camerarius demonstrated for the first time the existence of sexual reproduction in plants and in the middle of the 18th century the German botanist Josef Kölreuter described the "hybrid vigor" i.e. the effect of heterosis as it is called today when two morphological distinct plants from the same species are cross-fertilized. He also produced the first hybrid crop variety. In the USA, in 1825, John Lorain, described the possibility of growing hybrid corn and that such a crop would deliver

1 MURPHY, Denis. *Plant Breeding and Biotechnology, Societal Context and the Future of Agriculture*. Cambridge: Cambridge University Press, 2007, p. 18 to 19.

higher yields and also that it would not be economically viable for farmers to save seed for replanting. With this Lorain highlights a business opportunity for specialized seed breeders. However it took another century until this concept became a viable commercial proposition[1].

During the 20th century a number of interesting new technologies for crop breeding were developed such as cell fusion (1909), quantitative genetics (1918), chemical mutations (1927), X-ray mutagenesis (1928), in vitro tissue culture (early 1940s), mass clonal propagation (1950s)[2]. The latest development of genetic engineering or transgenesis also described as genetically modified organism (GMO) appears as a step in a sequence of the development of new tools and technologies used in plant breeding and plant improvement. In this paper, the legal treatment from a perspective of intellectual property rights of the two technologies a) mutagenic breeding and b) transgenesis will be analyzed. These two technologies can be both used for a variety of purposes. However, the scope will be limited to a comparable application of the two technologies, namely as a tool to create herbicide tolerant/resistant plants and how such an invention can be protected.

Initially there will be a review of the development of legal protection mechanism for plants and for biotechnological inventions from a global perspective, global agreements such as the TRIPs agreement (Trade-Related Aspects of Intellectual Property) and its application in Brazil and other countries namely the USA and the European Union.

There will further be a focus on rice with some comparable analysis to other crops where the two above mentioned technologies are being applied namely corn, soybeans and wheat. There will also be a discussion about the legal interpretation versus a more technical interpretation for the purpose of patent application of terms like "transgenic micro-organism" and "essentially biological processes".

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2 Id. at p. 15.

2. The Case

Currently there are five transgenic events released for commercial use according to information from the CNTBio (National Technical Center of Biosecurity) website[3]:

1. Monsanto, Round-up Ready®, herbicide tolerance technology for the glyphosate herbicide tolerance in soybeans
2. Bayer, Liberty-Link®, herbicide tolerance technology for the glufosinate herbicide tolerance in corn
3. Monsanto, Guardian Corn® Bacillus thuringiensis (Bt) based insect control for corn
4. Monsanto, Bollgard®, Bt based insect control for cotton
5. Syngenta, Maizgard®, Bt based insect control for corn

Bayer has also applied for the use a transgenic herbicide tolerance technology in rice also branded as Liberty-Link®. The use of this technology in rice is currently not approved.

Herbicide tolerance achieved through mutagenic breeding does not require special regulatory approval and evaluations by the CNTBio with the exception of the normal herbicide registration procedures. The leading mutagenic herbicide technology has been developed for a number of crops with herbicides belonging to the group of the Imidazoline group (IMI). In Brazil the technology is commercially available for rice and corn and is being commercialized under the brand Clearfield® by the BASF Company. The development of IMI mutagen however has been done by different institutions mainly by public institutions and later been licensed to American Cyanamid, an agricultural chemical company later acquired by BASF Company.

In case of the rice mutagen the inventor is Louisiana State University, USA (LSU). In Brazil LSU filed its patent application at the INPI under # PI9708839-0. A second inventor of the same technologi-

3 CTNBio website www.ctnbio.org.br accessed on 28.12.2008.

cal principle also for rice is Instituto Nacional de Technologia Agropecuaria, Argentina (INTA), which holds the patent application # PI0412917-8 at the INPI.

These technologies, regardless of whether they are transgenic or mutagenic, deliver considerable benefits to the farmer and in some cases represent novel solutions to problems to which previously to the introduction no adequate alternative solutions has been available e.g. the control of a weed commonly known as "red rice" which is infesting normal commercial rice production fields. With the Clearfield® technology red rice can now easily and economically be controlled.

Seed is used in this and in many other cases as the delivery system to carry the technology to the farm gate and make it available for the farmer. For the incremental benefits derived from the use of the technology the farmer is charged a premium. Ideally the charge of royalties and technology fees is included in the seed price. This concept of value capture has been well accepted for technologies that are sold with hybrids seed such Bt hybrid corn and Clearfield hybrid rice and hybrid corn. Farmers usually do not save seed from a hybrid crop (produced from different male and female parental inbred lines) since the resulting second generation (F2) of a hybrid crop naturally segregates and delivers a much lower performance than the original hybrid seed in its first generation (F1).

This situation however is very different for variety seed such as soybean, rice and wheat. For planting rice farmers used traditionally variety seed. In 2004 RiceTec launched hybrid rice in the Brazilian market. The same company made also hybrid rice available in the US market. The development of rice varieties is done almost exclusively by public institutions such as the federal research station Embrapa and State research stations such as IRGA in Rio Grande do Sul (RS) and Epagri in Santa Catarina (SC).

Farmers tend to save the same grain produced from their variety seed for the next season's crop, the so called "farm saved seed".

Farm saved seed has been an intellectual property issue for a long time and prevented major investments from the private sector into this type of crops. The problem initially focused on the property rights of the seed. With the introduction of specific added value traits, these traits also have become an issue for IP law makers.

The private industry has focused its research investments into the development of hybrid seed, namely corn, sunflower, sorghum and more recently now also rice. Hybrids have been long recognized as the best biological means to prevent the use of farm saved seed.

No economically viable hybrid systems have yet been developed at a reasonable commercial scale for soybeans, wheat and cotton.

With the introduction of Round-up Ready soybeans (RR soybeans) and Clearfield variety rice (CL rice) farmers have quickly moved to the adoption of farm saved seed, with the main purpose of avoiding payment of the technology premium or royalties and securing adequate availability of seed containing the technology traits for the following season.

Technology owning companies have engaged in legal actions alleging patent infringement e.g. Monsanto Justice Court RS[4] case 70017712181 and BASF Justice Court RS cases 71001931351 and 71001904812.

2.1. Patent infringement and royalty collection — Roundup Ready Soybean

In the above cited decision No 70017713181 from March 26 2007 at the Justice Court of Rio Grande do Sul in which Monsanto do Brasil accuses the agricultural cooperative Cotricampo of not having collected royalties for the illegal use of patented Roundup Ready (RR) soybeans.

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4 State Court of Rio Grande do Sul www.tj.rs.gov.br accessed on 29.12.2008 .

Patents in Question**:**

Patent Number## Patent information obtained from the website www.inpi.gov.br accessed on 18.01.2009.#	Patent Object	Patent Validity[4,5]
PI11000007-4	Chimeric (transgenic) gene, vector to transform plants, method to produce plasmid*	Original deposit in the USA 07/08/1985 validity in Brazil 07/08/2005 extended to 10/7/2007
PI1101045-2	DNA sequence to intensify transcription efficacy	Original deposit in the USA 13/01/1987 validity in Brazil 31/01/2007, request for extension *sub judice*
PI1101063-0	Promoter for transgenic plants	Original deposit in the USA 31/10/1989 validity in Brazil 31/10/2009, request for extension *sub judice*
PI1101067-3	DNA construction to improve transcription efficacy	Original deposit in the USA 14/05/1997 validity in Brazil 14/05/2007, request for extension *sub judice*
PI1101070-3	Chimeric genes to transform plant cells using viral promoters	Original deposit in the USA 17/01/1983 validity in Brazil 17/01/2003

*"Chromosome" is a rather loosely defined term. In prokaryotes (bacteria), a small circular DNA molecule may be called either a "http://en.wikipedia.org/wiki/Plasmid" \o "Plasmid" or a small chromosome.[5]

In a first instance, the judge upheld the demand to declare illegal the collection of royalties or indemnification for the unauthor-

5 Definition from http://en.wikipedia.org/wiki/Chromosome accessed on 18.01.2009.

ized use of technology. However in the second instance the judge concluded that: a) while farmers made use of technology, the technology owner did not have the authorization to exploit that technology, b) there was contradiction and suppression in the judgment of the patent rights, c) that Law 9279/96 ensures the right of the appellants to prohibit to use, commercialize, condition, save grain and seeds for whatever commercial use and they are entitled to claim compensation.

However the judge also concluded that since the Monsanto technology is the only available technology for that purpose with a market share of 80%, customers do not have a choice and pursuant to Law 8884/94, which regulates economic abuses, limited the maximum value that Monsanto is allowed to charge on harvested soybean containing the RR technology.

It will be interesting to see if Monsanto can sustain a technology fee collection after all related patents have expired.

2.2. Royalty collection on mutagenic Clearfield Rice technology

Mutagenic imidazolinone tolerance for rice (Clearfield Rice, CL) has been developed by the Louisiana State University USA (LSU). A patent has been applied for and published on 30/06/1998 (Patent 5773704). In Brazil under PI9708839-0 the same patent has been applied for on 28/04/1997 claiming the following invention: "Process to control rice plants next to rice plants". The patent application was rejected three times according to the latest information. According to the information at the website of the INPI this patent has not been granted due to not fulfilling the legal requirements for a patent (decision on 14.10.2008).

Patent research revealed that INPI tends to reject this type of patent application on the basis of Law 9279/96 Art. 18 (III) regarding the non-patentability of living beings.

When the CL technology was launched in 2003, rice farmers in Rio Grande do Sul started to save seed in the very first season making use of the established tradition of saving seed for own use, based on the farmers rights as established in Art. 10, I of the Brazilian law No. 9456 on the protection of cultivars.[6]

Motivated by the ultimate success of Monsanto in its RR soybean case, BASF made attempts to collect royalties not only on certified seed, but also on the harvested rice grain which contains CL technology. Farmers which had used farm saved seed containing the CL technology and rice mills which received grain containing CL technology were intimidated. A large number of farmers and rice mills filed a suit against IRGA and BASF.[7] Farmers questioned the validity of the patents and hence the right to collect royalty. The cultivar in question is IRGA 422 CL which has been protected under the plant protection law[8]. The farmers have also questioned the legitimacy of royalty collection on the variety per se, arguing that IRGA's research is funded with farmers' contributions. Justice decided not to pursue this lawsuit for criminal patent infringement until the conclusion of the civil case questioning the validity about the legitimacy of the patents in question.[9]

The two cases, the RR soybean technology and the CL rice technology have in common, that they both cause tolerance to herbicides which otherwise could not by applied and thus deliver a considerable benefits to farmers. Both technologies the transgenic and the mutagenic technology have been widely described in the literature, yet as we will see in the following INPI treated transgenic technol-

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6 BRAZIL. Law No 9456 from April, 25th, 1997. Cultivar Protection Law. Published on April, 8th, 1997. Brasilia/ DF.

7 State Court of Rio Grande do Sul, Case Number 1070038621. Available at www.tj.rs.gov.br.

8 BRAZIL. Law No 9456 from April, 25th, 1997. Stablishes Cultivar Protection Law. Published on Federal April, 8th, 1997. Brasilia/ DF.

9 State Court of Rio Grande do Sul. Case Number 71001931251 2008/Crime dated 15.12.2008.

ogies more favorable in recognizing them as patentable inventions whereas applications for inventions based on the use of mutagenic technology has so far been granted in just one case.

3. The convergence of plant breeding and intellectual property

In Holland, the first dedicated vegetable seed companies started to operate between 1800 and 1810 and various other seed companies were founded in the 19th century according to WALTER SMOLDERS[10]. It is interesting to observe that private business initiatives in the seed sector started with higher value vegetable seed and not with the high volume, low value staple food crops such as wheat and corn. The most likely reason is that at this time there was no intellectual property that would ensure a continuous reward for crop improvement work. With the first presentations of hybrid corn in the USA to the farmers, breeders recognized two aspects a) improved yield and other agronomic benefits and b) the possibility of a sustainable plant breeding business since farmers move away from farm saved seed to hybrid seed that will have to be purchased annually[11].

In 1899 at an international conference on hybridization organized by the Royal Horticultural Society the leading British judge, Lord Justice Lindley made the following prediction:

> I have heard something about hybridization of which I know little. I have heard something which leads me to suppose that the development of that art may react with the profession to which leads me to suppose that the development of that art may react with the profession to which I have the honour to belong. Without being a prophet,

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10 SMOLDERS, Walter. Disclosure of Origin and Access and Benefit Sharing: The Special case of seeds for food and agriculture, Occasional Paper 17. Geneva. Available at www.quno.org .

11 MURPHY, Denis, *supra* note 1 pp. 23-26.

> I seem to see before me a vista of patent hybrids! What a treat for the patent lawyers! (ANON 1909 quoted by J.M. DUNWELL).[12]

The hybrid technology thus is a biological mechanism to prevent the reuse of farm seed and ensure the "copyright". This however did not resolve the issue for variety crops where farmers have a long tradition of saving their seed. The seed industry, in terms of IP, can be compared with the software industry. Both industries have in common high fixed overhead costs with research and development. The user can easily and at very low costs copy the products. A great deal of knowledge is not required to do it.

In the 1990s the biotech industry developed other genetic means to prevent the unauthorized reuse of farm saved seed namely the Genetic Use Restriction Technologies (GURT)[13]. This technology which has been labeled "Terminator Technology" received very bad press. Seed that contained GURT technology would result in a harvest of sterile seeds and thus not germinate in the following crop. Non-governmental organizations out-cried and caused governments to prohibit the use of GURT technology and caused the industry to withdraw the use of this effective biotechnological protection tool. Monsanto the owner of the GURT technology was forced to make public announcements: in 1999, Monsanto's former CEO stated, "we are making a public commitment not to commercialize sterile seed technologies, such as the one dubbed 'Terminator.'". In 2006, Monsanto made a new statement "we stand by our commitment to not use genetic engineering methods that result in sterile seeds. Period."[14]

Activists such as Canadian Pat Mooney were very successful in achieving negative publicity for the Terminator technology. Oppo-

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12 DUNWELL J.M., *Patents and Haploid Plants*, in TOURAEV A. et al. *Advances in Haploid Production in Higher Plants*. Springer Science+Business Media B.V, New York, 2009.

13 AOKI, Keith. *Seed Wars, Controversies and Cases on Plant Genetic Resources and Intellectual Property*. Durham: Carolina Academic Press, 2008, p. 103.

14 Information from http://pt.banterminator.org/Noticias-Atualizacoes/Noticias-e-atualizacoes/Monsanto-Acquires-Delta-Pine-Land-and-Terminator accessed on 30.12.2008.

nents argued that the Terminator technology supports a monopoly position of current market leader and in addition provides a monopoly beyond any patent or plant variety.[15]

The examples above show how the industry tried to develop biological barriers to better protect its germplasm and technology which is incorporated into the seed. While breeders and biotechnologist have developed biological means to protect their breeding work, new regulations, protection and patent laws and international treaties started to develop basically over the last 80 years.

The first IP convention, in Paris, in 1883 already envisaged not only industrial inventions but also agricultural products. MICHAEL BLAKENEY[16]:

"Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce, 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".

The main purpose to include these agricultural products within the Paris Convention was for the purpose of protection trademarks[17].

3.1. Patents in Plants

In 1930: the US Plant Patent Act (PPA) (35 USC §§ 161 — 164)

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15 The Relationship Between Intellectual Property Rights (TRIPS) and Food Security. Queen Mary Intellectual Property Research Institute. London: June, 2004, p. 84. Available at www.qmul.ac.uk.

16 BLAKENEY, Michael. *Plant Variety Protection, International Agricultural Research, and Exchange of Germplasm: Legal Aspects of Sui Generis and Patent Regimes*, Chapter 4.6 in Intellectual Property Management in Health and Agricultural Innovation. California: PIPRA University of California, p.401. Available at www.iphandbook.org,

17 *Ibid*.

was the first inclusion of biological agricultural innovations, which gives exclusive rights to patent asexually reproduced plant material (excluding plants that are propagated by tubers such as potatoes)[18]. Fruit trees, ornamentals and berries are usually propagated asexually. At that time it was considered that sexually reproduced varieties propagated through seeds, such as corn, rice, soybeans, sunflower and wheat, lacked genetic stability along generations and were excluded. Section 161 defines that: "Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids and new found seedlings other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor"[19]. The interesting part of this article is, that both inventions and discoveries are covered and also explicitly mutants, but restricted to asexually reproduced plants.

Alternative to patent protection, the so called *sui generis* (of its own kind or class) in form of Plant Variety Protection (PVP) regulations started to be discussed. The Congrès Pomolique de France, held in 1911, called for special protection for plant varieties[20]. Discussions continued through the 1920s and 1930s cumulating with the foundation of the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL) in 1938 in Amsterdam [21]. A number of conferences followed in 1956 and 1957 until finally in 1961, the International Convention for the Protection of new Varieties of Plants, commonly used in the French abbreviation UPOV (*Union pour la Protection de Obtentions Végétales*).

This convention recognized the legitimacy of breeders' rights and established as a pre-condition for protection, that a variety be distinct from pre-existing varieties and sufficiently homogeneous and

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18 SMOLDERS, Walter, *supra* note 11, p. 8.

19 USA Plant Patent Act of 1930. (35 USC §161). Available at http://www.bitlaw.com/patent/rights.html accessed on 30.12.2008.

20 BLAKENEY, Micheal, supra note 17, p. 402.

stable[21]. This convention includes all botanical genera and species regardless of whether they are sexually or asexually reproduced.

The convention was then amended and exist today in two forms a) the 1978 Act and the b) the 1991 Act. Before 1978 only twelve member states had signed up. The convention requested a member country to establish either a plant patent or a *sui generis* UPOV-style protection for plant varieties. With the 1991 Act., Art 2 of the convention was amended to allow access of countries like the USA which had laws allowing for the double protection of varieties under both patent law and UPOV-style[21].

The USA issued in 1970 the Plant Variety Protection Act (PVPA) for sexually and tuber propagated material.

3.2. The TRIPs Agreement and its application in national legislations

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an "http://en.wikipedia.org/wiki/International_agreement" \o "International agreement" administered by the "http://en.wikipedia.org/wiki/World_Trade_Organization" \o "World Trade Organization" (WTO) that sets forth minimum standards for "http://en.wikipedia.org/wiki/Intellectual_property" \o "Intellectual property" regulation. It was negotiated at the end of the "http://en.wikipedia.org/wiki/Uruguay_Round" \o "Uruguay Round" of the "http://en.wikipedia.org/wiki/General_Agreement_on_Tariffs_and_Trade" \o "General Agreement on Tariffs and Trade" (GATT) in 1994. It is the first and only intellectual property right treaty, which seeks to establish universal, minimum standards for protection across the major fields of intellectual property, including patents, copyrights, trademarks, industrial design, integrated circuits and trade secrets[21]. Brazil had a period of four years to adhere but decided per Presidential De-

21 SMOLDERS, Walter. *Supra* note 11, p. 8.

cree to adhere immediately to the treaty (Decreto 1355/94). KELLY LISSANDRA BRUCH.[22]

> The TRIPS Agreement requires Member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced.[23]

The TRIPS agreement allows member countries three permissible exceptions to the basic rule on patentability:

> a) for inventions contrary to *ordre public* or morality; this explicitly includes inventions that are dangerous to human, animal or plant life or health or seriously prejudicial to the environment. (Article 27.2)[24];
> b) members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals (Article 27.3(a)) [24]; and
> c) member countries may exclude plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, any country excluding plant varieties from patent protection must provide an effective *sui generis* system of protection. Moreover, the whole provision is subject to review four years after the Agreement enters into force (Article27.3(b)) [24].

In particular Art 27.1 of the TRIPS agreement is subject to international debate and controversy. Developing and emerging countries have taken a position against patenting plants and in countries that are members of the European Patent Office (EPO), the patenting

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22 BRUCH, Kelly Lissandra. *Limites do Direito de Propriedade Industrial de Plantas*. Porto Alegre: UFRGS, 200, p. 28.

23 Available at http://www.wto.org/english/tratop_e/TRIPS_e/intel2_e.htm#patents accessed on Jan 2 2009.

of varieties, per se, is prohibited[24]. The European Patent Convention (EPC) it its Art 53 (b) excluded plant varieties as well as "essential biological processes" from the scope of patentable subject matter[25]. However the EPO, Board of Appeals, determined, that a claim directed to transgenic plants of more than one variety, but not claiming an individual plant variety, is permissible for patent application[25].

The WTO has reviewed in 2003 the application of the Article 27.3(b). The report[26] reviews how the different member countries have applied the directives given under this article in their national legislation. A questionnaire was sent out to the member countries and the following countries did reply to the questionnaire: Australia, Bulgaria, Canada, Czech Republic, European Community and their member States, Hungary, Japan, Korea, Morocco, New Zealand, Norway, Poland, Romania, Slovenia, South Africa, Switzerland, United States and Zambia.

To the question: "In your territory, is there any basis for denying a patent on an invention consisting of an entire plant or animal that is novel, capable of industrial application, involves an incentive step and has been adequately disclosed?"

Only Australia, Japan, Romania, Slovenia and the United States answered "no" thus affirming the possibility of a patent on plants and/or animals.

To the question: "Is it possible to obtain a patent, in your territory on a micro-organism that is novel, involves an inventive step and is capable of industrial application?" All countries which had replied to the questionnaire replied with "yes".

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24 HENSON-APOLLONIO Victoria. *Patent Protection for Plant Material*, WIPO-UPOV Symposium on the co-existence of patents and plant breeders' rights in the promotion of the biotechnological developments, Geneva: WIPO-UPOV/SYM/02/4 English, 2002, p.3.

25 BLAKENEY, Micheal. supra note 17, p 407.

26 Review of the Provisions of Article 27.3(b) Illustrative List of Question. Report IP/C/W/273/Rev.1 of 9 March 2006.

In Brazil the Law 9279 as outlined in Chapter 2 in its Art 18 III follows the TRIPS agreement in allowing patents on micro-organism however restricted to transgenic micro-organism. The use of the term micro-organism in both the TRIPS and the aforementioned Brazilian law lacks a clear definition. MICHEAL BLACKNEY[27] argues that the lack of a commonly accepted definition Art. 27.3(b) in the TRIPS convention of the term "micro-organism" either in science or in patent office practice permits great variations and interpretations among member countries leading to partial exclusions.

S.K. VERMA[28] an IP Professor at the University of Delhi, India comments that since the above mentioned Art 27.3(b) fails to define the terms, micro-organism, non-biological and micro-biological processes, "developing countries can interpret these terms to suit their development goals, while meeting the over-all criterion of patentability as laid down in Art. 27.1". WTO members may adopt a scientific definition of micro-organism, covering viruses, algae, bacteria, fungus and protozoa[29]. S.K VERMA argues further, the issue of patentability of micro-organisms, non-biological material and micro-biological processes thus requires a clear definition of the TRIPS convention, which presently does not expressly include or exclude naturally occurring substances, such as genes and cells from patent protection. The TRIPS agreement does not make any reference to biotechnology. Member countries in their national legislation may include or exclude genes or DNA sequences as patentable subject matter or refuse patent for not being innovative enough since the technique employed has become routine.

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27 BLACKNEY, Michael. *supra* note 17 p. 412.

28 VERMA, Surinder Kaur. *Fitting Plant Variety Protection and Biological Inventions in Agriculture within the Intellectual Property Framework: Challenges for Developing Countries*. Hong Kong: UNCTAD/ICTSD/HKU/IDRC Regional Dialogue, 2004. Available at http://www.iprsonline.org/unctadictsd/dialogue/docs/Verma_2004-11-08.pdf accessed on 28.12.2008.

29 *Ibid.*

3.3. Patent Law for Micro-Organism

In the Brazilian Law 9279 the application of the TRIPS requirement to contemplate for patentability of micro-organism has been regulated in a Sole Paragraph under Art. 18. Sole Paragraph:

> For the purposes of this law, transgenic micro-organisms are organisms, except the whole or part of plants or animals, that present, due to direct human intervention in their genetic composition, a characteristic that cannot normally be attained by species under natural conditions.[30]

In contrast MICHAEL BLAKENEY, Director of the Queen Mary Intellectual Property Research Institute at the University of London, U.K. argues:

> The practice of patent offices in developed countries suggests that there is no perceived need for a definition: the key issue for protection being not its subject matter, but whether or not the invention meets the patent-granting criteria.[31]

MICHAEL BLACKNEY argues further that an invention involving biological material will be regarded as lacking an inventive step if it[32]:

> a) merely identifies the biological material; and
> b) merely identifies the natural function of the biological material.

An invention will demonstrate an inventive step if it takes the form of a significant technical application of an identified function of

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30 BRAZIL. Law nº 9279 of May, 14th, 1996. Rules the rights and obligations regarding Intellectual Property Law. Published on May, 15th, 1996, Brasilia, DF. Translated version available at http://www.araripe.com.br/law9279eng.htm#patsec3 accessed on 12.29.2008.

31 BLAKENEY, Micheal. *Supra* note 17 p.413.

32 *Ibid*.

the biological material. This technical application must go beyond the mere simple replication of the natural function of the biological material, and the technical application must represent a significant technical advance on the prior art.[33]

The invention must be capable of being used in a manner that provides a demonstrable public benefit. A public benefit is understood as being conducive to public health and to social, environmental, and economic welfare.[34]

3.4. The Scope of plant breeders rights according to UPOV-style PVP.

Generally member countries confer through domestic legislation for the holders of PVP certificates the exclusive right to do or to license[35]:

a) produce or reproduce the material;
b) condition the material for the purpose of propagation;
c) offer the material for sale;
d) sell the material;
e) import and export the material; and
f) stock the material for the purposes described above.

According to WTOs review on the provisions of the Article 27.3(b) of the TRIPS convention[36], all countries that have answered the questionnaire have an UPOV-type *sui generis* form of protection.

Under US law, anyone who develops a new plant variety may obtain one or two forms of protection: a) US Patent Act from 1930

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33 *Ibid*.

34 *Ibid*.

35 *Id.* at p. 403.

36 WTO. *Supra* note 27.

exclusively for asexually reproduced plant varieties (excl. tuber propagated plants) b) US Plant Variety Protection Act from 1970 for varieties that are sexually reproduced or through tuber propagation and c) regardless of its method of propagation, the developer of a new plant invention i.e. a plant variety or an invention concerning plants, may obtain a utility patent under the general patent law USC title 35 under Section 101 from the United States Patent and Trademark Office (USPTO)[37].

Following the adherence to the TRIPS convention in 1994 Brazil has implemented the current patent law No. 9279 in 1996 and the law No. 9456 in 1997, a *sui generis* type law based on the 1978 UPOV convention. Law No 9279 is governed by the INPI which is part of the Ministry of Development, Industry and External Trade the second Law No. 9456 is governed by the National Service of Cultivar Protection (SNPC) which is part of the Agricultural Ministry.

The breeder of a protected variety has a protection period of fifteen years with the exception of trees and vine for which the protection period is eighteen years (Art. 11)[38].

4. Utility Patents in the USA

As outlined above most countries do not grant patents on plants. Some countries such as the US and Australia provide that an entity may be granted a patent to exclude others from use of plants and plant products, provided that the legal criteria for patentability are met.

For over two hundred years living organisms were considered a"product of nature" and not a human invention and were therefore excluded from patent laws.

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37 WTO. *Supra* note 27 p. 33.

38 BRAZIL. Law No 9456 from April, 25th, 1997. Stablishes Cultivar Protection Law. Published on Federal April, 8th, 1997. Brasilia/ DF.

The non-patentable status of living organism changed with the US Supreme Court case in Diamond v. Chakrabarty in 1980[39]. The court decided in a narrow 5:4 decision that a genetically modified living organism, in this case an "oil-eating bacterium" useful for cleaning up oil spills is patentable. The Court majority reasoned that, "a live, human made organism is patentable subject matter" because humans can now with the newly developed genetic engineering techniques, develop such organisms not occurring in nature[40].

Following that important landmark decision in 1985 another US decision by the Board of Patent Appeals known as the Ex Parte Hibberd case changed history and continues to be discussed with regard to plant patents. Dr. K. Hibberd, a molecular genetics scientist, had applied for a patent on tissue culture, seeds and whole plant of a maize line selected from tissue culture. They concluded that the PPA and the PVPA did not limit Hibberd's ability to seek a utility patent if the Patent Act's requirements of novelty, non-obviousness, and usefulness are met[41]. With this decision the court declared that utility patents available to inventors since 1790 can also be applied to plants.

In the US, the Federal Court resolved any potential conflict between PPA and PVPA in its decision in the Pioneer Hi-Bred International Inc (Pioneer). See J.E.M. Ag. Supply Inc. (Farm Advantage) case. In this case Pioneer brought a patent infringement lawsuit against Farm Advantage, a small seed supply company based in Iowa USA. Farm Advantage purchased seed patented Pioneer corn hybrid seed from an authorized Pioneer seed dealer and for reselling the seed to farmers. Pioneer claimed that Farm Advantage had violated its exclusive right to make, use and sell its own proprietary hybrid seed during the patent term.[42]

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39 ACTIONBIOSCIENCE, DNA *Patents Create Monopolies on Living Organisations,* at http://www.actionbioscience.org/genomic/crg.htm accessed on Dec. 16 2008.

40 AOKI, Keith. Supra note 14 p. 42.

41 *Id.* p. 43.

42 *Id.* p. 46 — 49.

Farm Advantage objected that Pioneer had obtained both patent protection under PPA and certificates of protection under PVPA. Further the defendants argued that the enactment of the protection under PVPA had "removed seed-produced plants from the realm of patentable subject matter in the Patent Acts".[43]

The Federal Circuit rejected this argument based on a Supreme Court decision "when two statutes are capable of coexistence, it is the duty of the courts to regard each as effective".[44]

5. European Legislation and Cases on Patents on Plants

The European Patent Convention (EPC) ruled the exceptions in its Art. 53.

> European patents shall not be granted in respect of:
> (a) Inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
> (b) Plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof; and
> (c) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.[45]

In 1984 there was a first case on the distinction between plant

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43 BLAKENEY, Michal. Supra, note 17. p. 409.

44 *Id* p. 409.

45 Available at http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ar53.html accessed on Jan 9 2009.

and plant variety by the Technical Board of Appeal of the European Patent Office (EPO) in the Ciba-Geigy determination[46].

To a certain extent the "forerunner" of the herbicide tolerance technology was a concept called "Safener" in which a plant or a seed is treated with a chemical which then reduces the toxic effect a herbicide would have on the crop without the application of the "Safener". Thus seed treated with a "Safener" protection like a transgenic or mutagenic herbicide tolerance the crop form the herbicide effects while remaining effective against the weeds which are the target of the herbicide. The Examination Division originally refused the patent application on the basis of Article 53(b). The decision was then reversed by the Technical Board of Appeal, which applied the definition of plant variety in the UPOV Convention.

> Article 53(b) of the European Patent Law, 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.[47]

The European lead case for patenting transgenic plants is the Novartis/Transgenic case G1/98[48]. The application concerned a patent containing claims to transgenic plants comprising foreign genes which expressed antipathologically active substances which control plant diseases. The initial denial was supported by the Technical Board of Appeal on the grounds that EPC Art. 53(b) denies the patentability of an invention that embraces plant varieties.

The Board of Approval went through a lengthy analysis process and the following decisions were taken:[49]

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46 BLAKENEY, Michal *Supra* note 17 p. 408.

47 *Id* p. 408.

48 EU. EPO Official Journal, 3/2000, Decision of the Enlarged Board of Appeal dated 20.12.1999.

49 *Id* p. 136 — 141.

According to Art. 53(b) EPC, a patent is "in respect of plant varieties" and shall not be granted if the claimed subject-matter is directed to plant varieties.

Inventions concerning plants not restricted to a single variety but characterized by a particular gene (and not as whole genome) are not covered by the protection for new varieties (under PVP regulation) and are not excluded from patentability even if they comprise new varieties of plants.[50]

On the question of how to regard plant varieties as products of processes using recombinant gene technology the following explanation was given:

One could consider the genetic modification of plant material to be a micro-biological process within the meaning of Art. 53(b) and those excluded from patentability.

> Processes of genetic engineering however, are not identical to microbiological processes. The term, microbiological processes in the provision was used as synonymous with processes using micro-organisms. Micro-organisms are different from the parts of living beings used for the genetic modification of plants. On the other hand, it is true that cells and parts thereof are treated like micro-organisms under the current practice of the EPO. This appears justified since modern biotechnology has developed from traditional microbiology and cells are comparable to unicellular organism.[51]

This does not, however, mean that genetically modified plants are to be treated as products of microbiological processes within the meaning of Art. 53(b).[52]

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50 BLAKENEY, Michal *Supra* note 17 p. 418.

51 EU. **EPO Official Journal**. *Supra* note 49, Question 5.2. p. 138.

52 *Id* Question 5.3 p. 139.

The Board further concluded that, it does not make any difference for the requirements under the Regulation of Plant Variety Rights (UPOV Convention) how a variety was obtained, i.e., whether a variety was obtained as a result of traditional breeding techniques, or whether genetic engineering was used to obtain a particular new variety. The criteria under UPOV convention is: distinctness, homogeneity and stability.

In summary, the European Directive on the Legal Protection of Biotechnology Inventions permits the patentability of inventions concerning plants, where "the technical feasibility is not confined to a particular plant variety".[53] The G1/98 decision was an important decision for all inventors and companies active in the field of genetic engineering of plants. After this decision it has become possible to obtain broad claims directed to transgenic plants as long as they do not specifically relate to individual plants, comments HANS-REINER JÄNICHEN[54]

Comparing the Novartis/Transgenic case with the US Pioneer Hi-Bred International Inc versus J.E.M. Ag. Supply Inc. case, it can be noted, that both requested the competent patent boards to decide and to draw the line between PVP law and Patent law. The outcome of the decision between the old and the new world however is quite different. The US Supreme Court as mentioned above regarded valid the application of two non-exclusive laws i.e. the PPA and the PVPA. Whereas, the EPO Board of Appeal draw a line between plant varieties, which can be protected under PVP protection and plant related inventions not restricted to individual varieties that can be patented as long as the normal patent requirements are met.

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53 EU. **Directive on the Legal Protection of Biotechnological Inventions**, Article 4(1) para.2, 98/44EC O.J. L213/130, 1998 also in BLAKENEY, Micheal. *Supra* note 17 p. 418.

54 JÄNICHEN, Hans-Reiner. **The European Office will now Grant generic claims for transgenic plants**: G1/98, Plants/Novartis at www.vossiusandpartner.com/pdf/pdf_42.pdf accessed on Jan 9 2009.

6. Important differences between Patents (US) and PVP (UPOV) for cultivar protection

Source # KEITH	Aoki. *Supra* note 14. p.40.#, HUNTER, Robert. **News about patents**	licensing and seed capital sources for inventors and innovating organizations. at http://www.webpatent.com/news/news1_02.htm accessed on Jan 4 2009.#
Nature of Protection	Patents grant protection for a particular genotype and genetic sequences within. Protects from others making, using or selling the cultivar	Protects a particular phenotype, others cannot make commercial use of the protected cultivar, nor use a protected cultivar for the regular production e.g. as a parental line in a hybrid
Requirements	Patent requirements are: novelty, utility and non-obviousness	A certificate is given for a new, distinct, homogeneous and stable cultivar. No requirements for usefulness
Disclosure of Origin	Yes, a patent application must describe the plant with specificity and enable others to "make and use" the plant after the patent term expires	UPOV convention has no such provision. In Brazil L9456 Art. 14 (III) requires a description of the genetic origin.
Breeders Exception	No, other breeders cannot use a patented line in their breeding and research programs	Yes, other breeders can use protected lines for further breeding and make improvements (essentially derived cultivars)
Farmer Exception	No, farmers using farm saved seed are infringing patent rights	Yes, farmers have the right to save seed for own use and non-commercial use. In Brazil small farmers are also entitled to commercialize farm saved seed (L.9456 Art. 8, IV)

Seed Deposit	Requirement for a deposit of biological material (e.g., seeds or tissue culture), if the biological material is required to practice the invention	Depending on national legislation, seed deposit normally required for examination and as testimonials in case of infringements.
Third party access of seed	Must be accessible to the general public during the term of the patent	No such requirement. Inbred lines of hybrids can remain confidential long after legal protection has expired

7. Patent limitations on biotechnological inventions, a comparison between Brazil, the European Union and the USA.

In the United States, biotechnological inventions ranging from human gene therapy to genetically engineered plants and animals as well as processes for their production, are all within the scope of patent eligible subject matter. Worldwide, the US patent law provides the broadest protection to biotechnological inventions. JASEMINE CHAMBERS.[55]

To be patent eligible, a biotechnology invention must fall within one of the four classes of subject matter: process, machine, manufacture, or compositions of matter.[56]

In the European Patent Convention, in the previously mentioned Art. 53 the exceptions are defined: (a) contrary to *ordre public* and morality (b) plant or animal varieties or essentially biological processes, excluding however microbiological processes.

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55 CHAMBERS, Jasemine, **Patent eligibility of biotechnological inventions in the Unites States, Europe, and Japan: How much patent policy is public policy?** At www.findarticles.com/p/articles/ accessed on Jan. 9 2009.

56 USA **United States Code 35 Section 101** www.bitlaw.com/patent/rights accessed Jan 9 2009.

In Brazil the patent law No 9279 has two articles that define the limitations:

> a) Art 10. defines what cannot be considered to be inventions or utility models:
> Section IX — natural living beings, in whole or in part, and biological material, including the genome of germplasm of any natural living being, when found in nature or isolated from nature, and natural biological processes;[57] and
> b) Art 18 defines what is not patentable (I) contrary to *ordre public* and morality (II) substances, matter, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes of obtaining or modification thereof, when resulting from the transformation of the atomic nucleus (II) living beings, in whole or in part, except transgenic micro-organisms meeting the three patentability requirements — novelty, inventive activity and industrial application — as provided in Article 8 and which are not considered mere discoveries.[58]
>
> Sole Paragraph of Art 18:
>
> For the purposes of this law, transgenic micro-organisms are organisms, except the whole or part of plants or animals that present, due to direct human intervention in their genetic composition, a characteristic that cannot normally be attained by species under natural conditions.[59]

The definition "transgenic micro-organism" can be interpreted in a broader sense. Institute Dannemmann Siemsen[60]. While the Law

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57 BRAZIL. Law nº 9279 of May, 14th, 1996. Rules the rights and obligations regarding Intellectual Property Law. Published on May, 15th, 1996, Brasilia, DF. Translated version available at http://www.araripe.com.br/law9279eng.htm#patsec3 accessed on 12.29.2008.

58 *Ibidem*.

59 *Ibidem*.

60 IDS Instituto Dannemann Siemsen de Estudos de Propriedade Intelectual. **Comentários a Lei da Propriedade Industrial**. Rio de Janeiro: Livraria e Editora Renovar Ltda, 2005 p 48-49.

No. 8974 from January 20 1995 on Biosecurity is very specific and restricted to genetically modified organism (GMO's), Law No 9279 is not specific about the techniques applied to obtain the "direct human intervention". This difference seems to indicate the intention of the legislator to not restrict the patent law to the application of particular techniques of genetic engineering. In theory, any technique that has the consequence of a change in the genetic composition of a micro-organism by direct human interference may for the purposes of this law result in transgenic microorganisms.[61]

While the EPC makes an exemption for "microbiological processes", the Brazilian patent law makes an exemption for the "transgenic micro-organism". In both cases the term "microbiological" and respectively the term "micro-organism" will ultimately have to interpreted as "cells and parts thereof" as outlined in the chapter "European Legislation" in both cases varieties are restricted to obtain a patent. Also in both cases i.e. Brazil and EU legislators have foreseen for varieties the exclusive form of protection of UPOV types of law.

8. Patents on biological processes

The concept of PVP protection for plant and animal varieties has been re-defined by the EPO board in the Novartis/Transgenic case with the G1/98 decision.[62] The definition of "essentially biological processes" lacks clarification in some aspects MICHEAL KOCK.[63]

The two keys to successful breeding are variation and selection. We can distinguish between i) naturally existing variations e.g. cultivars, breeding lines, landraces and wild relatives and ii) induced variation such wild crosses, hybrids, mutagenesis, double haploid

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61 Ibidem.

62 EPO. *Supra* note. 49.

63 KOCK, Micheal. *Essential biological processes: the interpretation of the exception under Article 53(b) of the EPC*. **Journal of Intellectual Property Law & Practice**, 2007 p. 287.

techniques, tissue culture and transgenesis.[64] Through these activities the breeder develops and creates his raw material which then is screened through a selection process. This selection process was traditionally only mainly in the field through visual selection in field trials. With the development of new application in biotechnology the selection process is partly done also in the lab mainly to assist field selection or to pre-select according to given criteria's. Biotechnological tools nowadays include genome research (in modern "http://en.wikipedia.org/wiki/Molecular_biology" \o "Molecular biology" the genome of an "http://en.wikipedia.org/wiki/Organism" \o "Organism" is its hereditary information encoded in "http://en.wikipedia.org/wiki/DNA" \o "DNA" (or, for some viruses, "http://en.wikipedia.org/wiki/RNA" \o "RNA"))[65] and proteome research (field which studies the complexity and dynamics of proteins in biological systems, it combines powerful separation and analytical technology with advanced informatics to understand the function of proteins in the cell)[66]. Other tools are gene mapping, market assisted breeding and bioinformatics. Thus modern technologies are applied in both the initial raw material creation process which has the objective to generate variability and then in the following selection process which aims at the identification of new varieties with new or improved characteristics, traits, mutants or transgenic events.

"The fruit of inventive research into new plant varieties is literally and figuratively a simple yet high-tech product: seed" MICHEAL KOCK.[67]

The selection process becomes an element of a process and may fall within the exception, if the process is considered essentially

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64 MURPHY, Denis. *Supra* note 1 p. 14.

65 Available at "http://en.wikipedia.org/wiki/Genome,%20%20accessed%20on%20Jan.%209". 2009.

66 WILKINS, M.R. **Proteome Research**. About this book, at www.springer.com/life+sci/biochemistry.

67 KOCK, Micheal. Supra note 66 p. 287.

biological. The process applied in the development of a new variety or a new technology may not be on grounds of transgenic techniques (as required by the Brazilian patent law) and may combine natural i.e. biological processes (as excluded by the EPC) such as conventional crossing, and may be followed by a technical selection step e.g. marker assisted selection. The generation of a new herbicide tolerant variety may start with an induced mutagenesis through radiation, followed by a natural selection which then again is followed by marker assisted selection to accelerate the process. This leads to the conclusion that there is a protection gap for breeding processes and its outcomes when not restricted to individual varieties.

> The EU Biopatent Directive: "The protection conferred to a patent on a process that enables a biological material to be produced on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process through propagation or multiplication in an identical or divergent form and possessing those same characteristics.[68]

This patent extension to products is only granted for methods of manufacture, not for screening methods or methods of analysis. The selection method is likely to be interpreted as a method of analysis, a corresponding patent claim may not extend to products resulting from that method.[69]

MICHEAL KOCK argues further that:

> The limitations [in the EPC Art. 53(b)] to essentially biological processes and the exemption for microbiological processes demonstrates that other breeding processes should remain patentable. The EPC Working Party explicitly recognized that European patents had to be granted for breeding processes that are of a technical nature. Processes for

68 **Official Journal EPO** 1999, 101 Art. 8 (2).

69 KOCK, Michael. Supra note 66 p 288.

producing a new plants by irradiation (e.g. to induce mutagenesis) of the plants themselves or the seed with isotopes are cited as an example of such processes.[70]

An interesting observation is that even at the Strasbourg Convention (1963) it was understood that some processes, although based on biological material, are technical. The fermentation process has been used for millennia and its patentability has been recognized at least for 150 years[71], probably because of good lobbying of the cheese and wine industry.

Despite the explicit exclusion of subject matter that is isolated from nature in Law 9279 Art 9, IX, the process used for isolation, if it meets the requirements of patentability (novelty, inventive activity and industrial application), may be patented, since the Art 18 which defines the patent exclusions, does not explicitly exclude isolation from patent protection.[72]

However, the term "isolated from nature" is no longer a simple discovery, but is likely the result of human intervention. Thus it may represent subject matter that is not available in nature from which it has been isolated and could therefore represent inventive merits. The law excludes subject matter that is isolated from nature, without further considerations, because it is believed that such subject matter already existed previously.[73] However processes which are not natural (i.e. technical) using living biological material are not included in this section, and can therefore be patented, provided they meet the requirements of patentability.[74]

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70 *Id* at p. 291.

71 *Id* at p. 294.

72 IDS Instituto Dannemann Siemsen de Estudos de Propriedade Intelectual. *Supra* note 63p 27.

73 Ibiden.

74 *Ibiden*.

The questions MICHEAL KOCK is relating as previously mentioned with regard to the combination of technical and biological processes with regard to the application of the EPC, can also be asked with regard to the Brazilian patent law.

9. Patent Protection for Haploid Plants

An example of an application of technical process in breeding represents also the double haploid technique, a technique that started to be used by breeders more recently than the mutagenesis.

J.M. DUNWELL a plant science professor at the University of Reading, UK, comments that the double haploid (DH) technology, also referred to as anther culture, has a history of about 20 years.[75] DH technology is defined as:

> Haploid genomes contain a single copy of each chromosome while diploid genomes have two homologous copies. Usually organisms with a diploid genome inherit one chromosome of the pair from each parent. Double haploid occurs by doubling of the haploid genome resulting in pairs of chromosomes that are identical, so homozygous at each locus. This can be created artificially, by using colchicine, which prevents separation at meiosis where the chromosome number would be halved. This procedure is useful during plant breeding because of the homozygous plants produced.[76]

Inbred lines in hybrid development have to be homozygous; the DH technology is a method to create a big number of homozygous plants. Therefore this is a method to create genetic variability. It can be characterized as a technical process but not a transgenic tech-

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75 DUNWELL, J.M. in TOURAEV A. et al. Patents and haploid Plants. Advances in haploid production in higher plants, Chapter 7 p. 97. Springer Science+Business Media B.V. 2009.

76 WIKI at http://wiki.answers.com/Q/How_does_double_haploid_differ_from_diploid accessed on Jan 9 2009.

nology. According to J.M. DUNWELL over 50 patents have been granted in North America (30 patents), Europe (2 patents), China (11 patents), Japan (9 patents), Russia (4 patents), Canada (3 patents) covering a wide range of food and fiber crops, vegetable crops and flowers.

The subject matter of these patents covers methods for anther and pollen culture, ovule culture, the use of specific haploid-inducing genes and embryo regulation genes.

A search at the website of the Brazilian Patent Office (INPI)[77] using above terms: *cultura de ovulo* (ovule culture), *doble haploid* (double haploid) *anteras* (anther) *processos biologicos* (biological processes) has not obtained positive results, which seems to indicate that either no DH related applications have been made or that the summary of the application does not include above terms related to a useful process for a crop.

10. Patent applications related to plant related mutagenic inventions

A search at INPI's website[78] on mutagenic plant patent applications produced the result summarized in the table below. Only one application based on mutagenic technology was granted (PI9202950-7). This patent is related to a process to confer IMI herbicide resistance to monocotyledonous plants, as example, gene DNA sequences for corn were developed. All other mutagenic related applications have either been rejected or have not yet analyzed.

77 INPI at www.inpi.gov.br pesquisa — patents accessed on Jan 9 2009.

78 INPI at www.inpi.gov.br pesquisa — patents accessed on Dec 27 2009.

Patent No Applicant	Patent Object	Patent Status
PI9105628-4 American Cyanamid	DNA sequence which encodes a functional AHAS enzyme which confers herbicide tolerance (mutagenesis not explicitly explained)	Deposit on 15.2.1992, Filed on 4.4.2000 due to abandonment of the case
PI9202950-7 American Cyanamid	Process to confer specific resistance to imidazoline in plant cells and process to produce a usable vector to confer specific resistance to IMI* herbicides of a hose cell. As an example such DNA sequences have been done for corn.	Deposit on 30.7.1992 Patent granted 11.7.2000 Transferred to BASF on 21.10.2008
PI9604993-6 American Cyanamid	Model for isolated DNA which codifies a protein variant in AHAS synthesis. Method to confer herbicide resistance.	Deposit on 19.4.1996 Third negative opinion on 25.9.2007
PI9708839-0 Louisiana State University	Rice plant and process to control weeds close to another rice plant	Deposit on 28.4.1997 Third negative opinion on 14.10.2008
PI9914939-7 American Cyanamid	Genes and vectors to confer herbicide resistance to herbicides in plants	Deposit on 5.11.1999 Not yet examined by INPI
PI0110410-1 BASF	Use of AHAS mutant X112 from IMI corn for the selection of transgenic plants of corn, rice and wheat resistant to IMI herbicides	Deposit on 27.4.2001 Filed on 19.8.2008 due lack of fee payment. Company has 3 months to remedy it
PI0413917-8 INTA Argentina	Plant and parts of rice plant, cells, seed, isolated AHAS nucleic acid, method to control weed plants close to a rice plant and for the production of a transgenic plant	Deposit on 30.8.2004 Not yet examined by INPI
PI0211808-4 University of Saskatchevan, Canada	Wheat plants with an increased tolerance to IMI herbicides	Deposit 10.7.2002 Not yet examined by INPI

* IMI = imidazolinone

Search Keywords: Rice and AHAS, control rice and red rice, monocots and AHAS, imidazolinona, mutagenic and rice/wheat/corn, herbicide and tolerance/resistance, (search in Portuguese)

11. Conclusions

From the RR soybean case, it can be observed, that a 20 year patent term from the first international grant is a short period for plant related inventions, which have to be inserted into local adapted germplasm, going through fields testing and other approval processes such as it is the case with transgenic technologies.

Only one patent application has been granted for a mutagenic invention. INPI has more easily granted patents on transgenic events, at least for the early applications.

Opportunities for patents are given through the option of a) transgenic micro-organism, b) technical processes and c) isolation from nature, if human invention can be demonstrated.

The inclusion of micro-organism and the exclusion of the natural biological processes are both a result of the TRIP's agreement to which Brazil adhered. National laws have interpreted these compulsory subject matters in different ways. It is generally understood that the interpretation should not be strictly technical but rather in terms of patent office practice. The term micro-organism is to be understood from a legal rather than from a biological definition, including transgenic cells and parts thereof.

In developed countries the key issue for protection is not its subject matter, but whether or not the invention meets the patent granting criteria.

If patent protection is rejected, trade secrets and material transfer agreements remain almost the only legal alternative to protect inventions.

The *sui generis* PVP protection provides a meaningful protection for plant varieties but not for invented technologies in the varieties which under this protection regime can be transferred to other varieties without further obligations to the inventor of such technologies.

GURT technologies that render sterile seed have been abandoned on political pressure. The hybrid technology a biological tool remains in practice a more effective protection tool than patent law in most part of the world.

The US patent law permits the patenting of "anything under the sun that is made by man"[79] providing the broadest protection of biotechnological inventions. Unlike other developing countries, Brazil introduced swiftly after signing the TRIPs agreement national laws for patent protection and *sui generis* plant protection. Yet this has not yet given sufficient incentives for national organizations and institutions, public and private to develop patentable technology. Most plant science related patent applications at the INPI are made by institutions from abroad.

While consumer and environmental groups oppose the liberation of transgenic technologies, inventors of these technologies have bigger chances to obtain patent protection.

On the other hand mutagenic breeding and trait development, a technology described first in the 1920s. This technology approach has continuously been sophisticated from a technology and process standpoint. Mutagenic breeding has the advantage of less regulatory approval and no opposition from consumer and environmental groups; however these types of inventions have been treated less favorably by the patent office.

The conflicting interests between chances of regulatory and society approval and the chances of patent protection, lead to a di-

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79 CHAMBERS Jaqueline. Supra note 58 p. 2.

lemma in particular for private but increasingly also for public companies and institutions. Companies and institutions allocating resources to the development of technologies that will advance agriculture and develop new means to secure food supply in future, have in Brazil a weak expectation for IP. This affects negatively the investment into the development of novel plant science related technologies.

The more generous approach taken by the US patent law and its application by the US patent office towards granting patents on plant inventions is contributing and motivating the allocation of research funds into new projects, supporting further the leading position of that country in agricultural biotechnology research and ultimately its economy.

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Abbreviations

BRL Brazilian Real

CL Clearfield a BASF registered trademark for herbicide tolerance technology

DH Doubled Haploid

EPC European Patent Convention

EPO European Patent Office

GATT General Agreement on Tariffs and Trade

GMO genetically modified organism

IMI Imidazolinione herbicides

INPI Instituto Nacional de Propriedade Industrial, Brazil (Nacional Patent Office)

INTA Instituto Nacional de Technologia Agropecuaria, Argentina

IP Intellectual Property

LSU Louisiana State University, USA

PPA Plant Patent Act (USA 1930)

PVP Plant Variety Protection, expression for UPOV related variety protection

PVPA Plant Variety Protection Act (USA 1970)

TRIPS Agreement on Trade Related Aspects of Intellectual Property Rights

UPOV International Convention for the Protection of New Varieties of Plants

USC United States Code

USPTO United States Patent and Trademark Office

WIPO World Intellectual Property Organization

WTO World Trade Organization