The Enola and Nuña Bean Patents in the Context of Intellectual Property Rights for Plant Cultivars

L. Pallottini,[a,c] E.Garcia,[b] J. Kami,[c] G. Barcaccia,[a] and P. Gepts[c]
[a] Department of Agronomy & Crop Science, University of Padova, Agripolis, Via Romea 16, 35020 Legnaro, PD, Italy
[b] Department of Food Science & Technology, [c] Department of Agronomy & Range Science, University of California, 1 Shields Avenue, Davis, CA 95616, USA

It is fair to say that the news that two patents awarded by the U.S. Patent and Trademark Office for beans have been met with incomprehension, if not downright consternation by the bean research community. The two patents are for the yellow seed coat as shown by the common bean cultivar Enola (Proctor 1999; Patent no. 5,894,079, 1999) and for popping (nuña or kopuru) beans adapted to temperate (U.S.) conditions (Ehlers and Sterner 2000; Patent no. 6,040,503, 2000). In addition, a Plant Variety Protection (PVP) certificate was also awarded for the Enola cultivar. The surprise caused by the awards of these IPRs (Intellectual Property Rights) is directly related to their perceived lack of novelty. This overview will address a number of topics, namely a brief historic overview of the introduction of IPRs on living organisms, the type of IPRs applied to crop cultivars, the specific cases of the Enola and nuña patents, and a discussion about some issues related to biodiversity and crop cultivar IPRs.

Once upon a time, crop genetic resources were considered to be the "common heritage of humankind" (Herdt 1999). These resources were exchanged freely and at no cost among colleagues, in the public, and across borders. This was only 25 years ago. In this time span, a complete sea change has taken place, which has led to the current situation in which genetic resources are now a commodity subject to market prices, intellectual property rights, and national sovereignty. How did this change come about? The signature event was probably a 1980 U.S. Supreme Court decision (the so-called Chakrabarty v. Diamond decision: U.S. Supreme Court 1980) that instated a patent for a Pseudomonas bacteria capable of degrading hydrocarbons or "crude oil," presumably to be used in clean-up operations after a spill. This capability was unknown among naturally occurring bacterium. The U.S. Patent Office had refused claims of the patent application pertaining to the bacterium itself, but the Supreme Court decided to uphold the application, arguing that patentable subject matter is "anything under the sun that is made by man." This included living organisms.

This Supreme Court decision was further clarified in 1985 by the *Ex Parte* Hibberd decision of the Board of Patent Appeals and Interferences (BPAI), specifically regarding crop cultivars. Plant breeders could now obtain a "utility patent" for their cultivar. It should be noted here that since 1930, plant breeders could patent vegetatively propagated cultivars, principally potato and horticultural species (the so-called "plant patents"). Plant patents did not cover, however, non-vegetatively propagated species. The impact of the 1980 Chakrabarty decision is not to be underestimated because it was on of the stimuli for the development of the biotechnology industry, including the migration of breeding programs from public institutions (in many cases, land-grant universities) to private companies, especially for field crops, such as maize, cotton, and soybean.

The plant and utility patents are not the only legal instruments to protect cultivars. Breeders can also obtain a Plant Variety Protection certificate from the USDA Plant Variety Protection Office. The PVP system is the practical consequence of the UPOV convention

(UPOV being a French acronym, which stands for the Union for the Protection of Plant Varieties). The treaty was first established in 1961, with additional revisions in 1978 and 1991. Most of the countries that have subscribed to UPOV are developed countries. An exception is Kenya. Increasingly, cultivars are protected by both patents and PVP.

What are the similarities and differences between patents (U.S. House of Representatives 2002) and PVP (U.S. House of Representatives 2003) with regard to crop cultivars? Both patents and PVP represent a compromise between society (represented by the government) and inventors. On the one hand, an inventor makes public his or her invention, including the way of manufacturing the invention ("enablement"). On the other hand, the government, in exchange for this invention, grants the inventor a temporary monopoly allowing the inventor to control his invention, by preventing unauthorized use, allowing him or her to award licenses and charge royalties, etc. The duration of this monopoly is 20 years for patents and PVPs for seed crops. For perennial crop PVPs, the duration is 25 years. For patents, the main criteria of patentability are Novelty, Utility, Non-obviousness (or inventiveness), and Enablement. For PVP, the main criteria are Distinctness, Uniformity, Stability, and Non-essential derivation. The latter criterion was added in the 1991 iteration of UPOV to explicitly state that changes to a cultivar such as introduction of a gene by backcrossing or genetic engineering do not qualify as major changes and, therefore, do not justify a change in ownership. Rather, the owner of the original cultivar also remains the owner of the "improved" cultivars with the minor changes. There is a grey area as to when a minor change becomes a major one, in which case a new PVP action would be warranted.

There are two important distinctions between patents and PVP. Unlike patents, PVP includes a farmer's exemption and a breeder's exemption. A farmer is allowed to harvest the seed and use it for free for further planting on his or her holdings. A breeder can use for free a PVP cultivar as a progenitor in crosses to generate the next generation of improved cultivars. Neither exemption exists for patented cultivars. In addition, courts have markedly reduced any research exemption associated with patents. The absence of the farmer's and breeder's exemption explains why patents have become increasingly popular as an IPR tool for cultivars the U.S. In Europe, only PVP can be used to protect cultivars. However, basic processes applicable to plants in general remain patentable.

Given this general background, what are the specific concerns associated with the Enola and nuña bean patents? For any patent, one needs to read carefully the specific "claims" described in the text of the patent because these determine the overall scope of the patent. For the Enola patent (Proctor 1999), the key claims are as follows:

"*1. A Phaseolus vulgaris field bean seed designated Enola as deposited with the American Type Culture Collection under accession number 209549.*
4. A field bean plant having all the physiological and morphological characteristics of the field bean plant of claim 2.
5, 6, 7: Also claims progenies of crosses …
8. A field bean variety of Phaseolus vulgaris that produces seed having a seed coat that is yellow in color, wherein the yellow color is from about 7.5 Y 8.5/4 to about 7.5 Y 8.5/6 in the Munsell Book of Color when viewed in natural light.
10. The Phaseolus vulgaris of claim 9 wherein the hilar ring has a color of rom about 2.5 Y 9/4 to about 2.5 Y 9/6 in the Munsell Book of Color when viewed in natural light.

Thus, the patent claims a specific genotype (of which a seed sample was deposited with the ATCC) and a (fairly narrow) range of shades of yellow seed coat color. According to the patents description, the genetic material was obtained in 1994 in Mexico in a bag of mixed bean seeds. The material was then grown out for three years in Colorado and underwent presumptive selection for uniformity and seed color, upon which both a patent and a PVP certicate were applied for in 1997 and awarded in 1999.

To investigate the origin and potential distinctness of the Enola genotype, a DNA fingerprinting was conducted. In this fingerprinting experiment, we considered three essential aspects: a) the plant sample; b) the marker type; and c) probability calculations. A sample of 56 domesticated bean genotypes was assembled. This sample included not only 24 yellow-seeded genotypes but also 32 non-yellow genotypes, which were included as controls, especially for the probability calculations. Among the yellow-seeded materials were Enola (obtained from the official sample at the American Type Culture Collection), three Peruano-type cultivars (Azufrado Pimono78, Azufrado Peruano 87, and Azufrado Regional 87), a few breeding lines of this market type, one representative each of the original yellow beans for Mexico and Peru, and Sulfur BN142 (a presumed representative of Sulphur, described by Hedrick, 1931). Voysest (2000) describes how Mexican bean breeders developed the new Peruano market class by crossing Mexican Azufrado and Peruvian Canario types and selecting for yellow seed color and growth habit.Among the non-yellow seeded materials were representatives of the six major races of domesticated beans.

The second aspect to consider in a fingerprinting experiment is the type of marker. *A priori* we thought that markers ought to obey the following conditions: a) highly polymorphic and/or high number of markers; b) reproducible; c) well-distributed throughout the genome; d) well-known pattern of genetic diversity in the gene pool of interest; and e) well-known and used in the research community. Given the current status of markers in beans, three types of markers could potentially qualify for this type of study: a) AFLPs; b) ISSRs; and c) Microsatellites. Of these, AFLPs come closest to fulfilling the requirements. They generate a large number of markers (which will prove essential in probability calculations), they are reproducible, and there is prior history of their use in common bean for the analysis of genetic diversity.

The third aspect is the calculation of the probability of a match between an Enola fingerprint and fingerprints of other bean cultivars, especially yellow-seeded cultivars. The general formula for calculating the probability of a match between two profiles is $\tilde{P} = \prod_i \tilde{p}_i^2$ (Weir 1996: p. 218), with $\tilde{p}_i 0$ being the probability of obtaining the *i*th fragment state observed for the Enola profile (either presence or absence of the fragment). (The squared frequency is used because the frequency of a match between two fingerprints is calculated instead of the frequency of a specific fingerprint.) This formula is valid only if AFLP fragments show independence among each other. We defined independent markers as those markers for which less than 10% of the Fisher exact tests for independence with all other markers were statistically significant ($P \leq 0.10$). This greatly decreased the number of markers available. From an original 133 markers, only 25 to 30 markers are generally independent from each other. The lack of independence of the other markers is due in part to linkage and in part to common ancestry and population structures (gene pools, market classes, etc.). The actual probabilities ($\tilde{p}_i 0$) depend on the breeding scenarios envisioned for the development of Enola. Four major scenarios were considered, based in part on the known history of the Peruano-type marker class in Mexico (Voysest 2000) (scenarios 1-3) and the patent description (scenario 4): 1) cross between any Andean and Mesoamerican genotype, regardless of seed color; 2) cross between an Andean and a Mesoamerican yellow-seeded genotype; 3) cross between any yellow-seeded type, principally Peruano types; and 4) selection within an existing yellow-seed cultivar. Further details are provided in an upcoming manuscript by Pallottini et al. (2004).

The main conclusions of this fingerprinting experiment were as follows (Pallottini et al. 2004). AFLPs were very useful in identifying differences or similarities even among closely related genotypes. AFLPs based on *Pst*I/*Mse*I primers revealed a three-fold larger number of polymorphic markers than those based on *Eco*RI/*Mse*I primers. AFLPs classified bean cultivars according to previously known relationships such as the split between Andean and Middle American cultivars (Fig. 1).

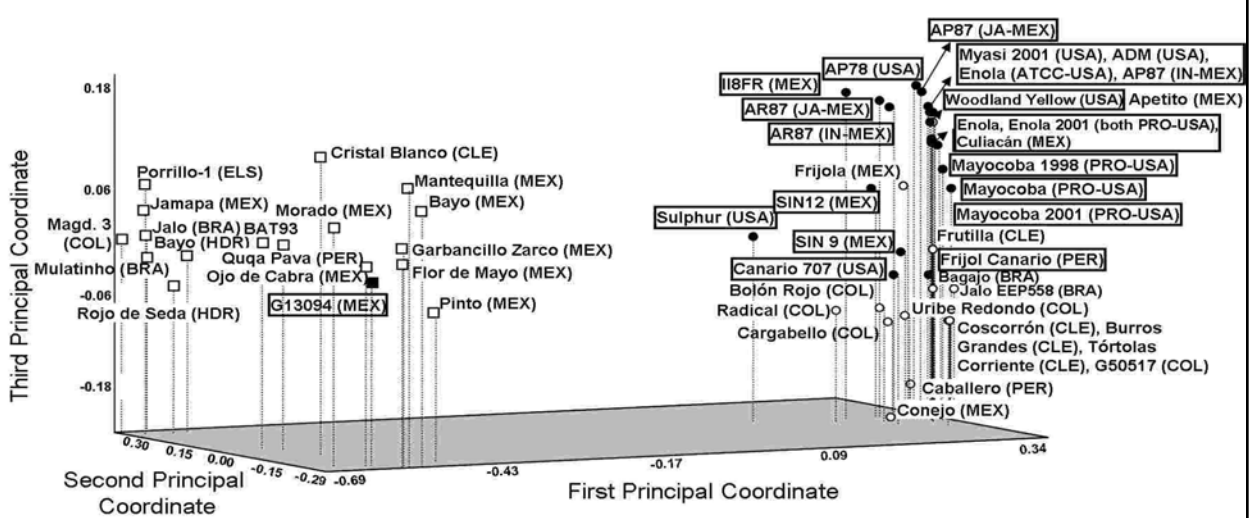

Fig. 1. Principal coordinate analysis of AFLP diversity in a sample of 56 common bean cultivars. Square symbols: Middle American gene pool; circles: Andean gene pool. Boxed entries and filled symbols: yellow seed coat entries. AP78: Azufrado Peruano 78; AP87: Azufrado Peruano 87; AR: Azufrado Regional 87. The eigenvalues of the three axes are 58%, 7%, and 5% (Pallottini et al. 2004).

They did not distinguish race Jalisco from race Durango cultivars in the Mesoamerican gene pool. No racial separation was observed in the native Andean cultivars as observed earlier (Singh et al. 1991). The Peruano group of cultivars fell within the Andean gene pool although it was distinct from the "native" Andean cultivars. Enola is part of the Peruano class of cultivars and is most closely related to Azufrado Peruano 87. In fact the probability of generating independently the same fingerprinting ranged from 1×10^{-18} (scenario 1) to 3×10^{-5} (scenario 3) to 3 x 10^{-1} (scenario 4: selection within Azufrado Peruano 87).

The PVP certificate cites the cultivar Azufrado Pimono 78 as the most closely related cultivar to Enola and mentions leaf color as a distinguish factor between the two cultivars. A replicated greenhouse experiment was conducted to compare leaf color among yellow-seeded cultivars, including Enola, Azufrado Pimono 78, and Azufrado Peruano 87 with a Minolta Chroma Meter CR-200 (Minolta, Ramsey, NJ), a tristimulus colorimeter. Of the three color variable measures L, Hue, and Chroma, only Chroma showed significant differences among means. Enola had lighter leaf color than one sample of Azufrado Peruano 87 but not the other sample. Thus, there is heterogeneity within the Azufrado Peruano 87 cultivar. The differences in leaf color between Enola and Azufrado Pimono 78 were not significant in this experiment. In any case, leaf color is a secondary character in the discussion surrounding Enola.

Our conclusion is that, from a genetic fingerprinting standpoint, Enola is not different from the pre-existing Mexican yellow-seeded cultivars. Furthermore, Bassett et al. (2002) have shown that the genetic combination controlling the yellow seed color in Enola (*C;J;g;b;vlae;Rk;gy*) is also present in the obsolete cultivar Wagenaar. These conclusions raise questions about the rationale for providing a utility patent or a PVP certificate to the Enola cultivar. Although we are not legal scholars, the data suggest that Enola does not satisfy the novelty and non-obviousness statutory requirements of the patent legislation. It may not satisfy the distinctness and non-essential derivation requirements of the PVP legislation.

So far, CIAT (Cali, Colombia) has challenged the award of the Enola patent by requesting a re-examination (introduced on Dec. 20, 2000). This was followed by a re-issue request on the part of the patentee on Jan. 31, 2001. The Patent Office has not yet ruled on these requests. Nobody has challenged the PVP certificate. Time is running out to do so because it can only be done within five years of the award, which took place on May 27, 1999.

Why were these intellectual property rights awarded at all, especially the utility patent? There has been an overall trend towards easier and broader award of patents. For example, as stated by Demaine and Fellmeth (2003), "*subtly and without fanfare, the prohibition on patenting products of nature has fallen into desuetude*." In the case of beans, there are at least two other patents that seem to be questionable in terms of novelty. For the nuña patent (Ehlers and Sterner 2000), the main claims are as follows:

" .... 9. A bean seed produced by a cross of a nuña accession and a Phaseolus vulgaris cultivar exhibiting the characteristics of early maturity, bush type growth habit, synchronous fruiting, and photoperiod insensitivity, wherein said bean pops at a moisture of about 5 to 12 percent.

10. A bean seed of claim 9, wherein said nuña accession is selected from the group consisting of accession numbers W6 4296, W6 4297, W6 4298, PI 298820, PI 298822, PI 298824, PI 316013, PI 316014, PI 316016, PI 316017, PI 316018, PI 316019, PI 316020, PI 316021, PI 316022, PI 316023, PI 316024, PI 316025, PI 316029, PI 316030, PI 316031, PI 316032, PI 390771, PI 390775, PI 511763, PI 511767, PI 531862, PI 577677, PI 577678, PI 577679, PI 577680, PI 577682, and PI 608402.

11. A bean seed of claim 9, wherein said Phaseolus vulgaris cultivar is selected from the group consisting of small white, small red, navy, dark red kidney, light red kidney, black or black turtle, pink, pinto, cranberry, and canario. ...." Neither of these claims is novel, nor would the combination of claims because it amounts to making crosses to introduce a trait from exotic germplasm into an adapted background. Furthermore, experiments have been conducted although perhaps not published that have attempted to introduce the popping trait. What is intriguing is that the Patent Office allows the patentees to claim accessions that are part of an official USDA germplasm bank. Even more intriguing is that the patentees could claim market classes, including the canario (yellow) seed type, thus raising the spectrum of infringement of the Enola patent.

The second case is a recent patent describing a method to decrease flatulence in legumes , in general, and in beans, in particular (Bush et al. 2002). The main claim is "*soaking a cleaned legume in a water bath having stagnant, sprayed or flowing water at a first temperature* [note: 90-130 ºF] *which is above ambient temperature but less than the critical rehydration temperature of the legume and under conditions effective to rehydrate the legume to at least 50% by weight of that of a fully hydrated legume; ….*" This procedure is very similar to the one used in households around the world to pre-soak beans in lukewarm water as a first step to cook beans with reduced flatulence.

In addition to the lack of novelty, the Enola and nuña patents also raise the issue of ownership of foreign genetic resources. In addition to the yellow and nuña bean patents, other controversial patents involving foreign genetic resources include the neem tree oil (Roland and Blouin, 1996), maca (DeLuca et al., 2000; Zheng et al., 2001, 2002), turmeric (Das and Cohly 1995), ayahuasca (Miller 1986), and basmati rice (Sarreal et al., 1997). Their existence suggest that more stringent criteria should be developed for such awards, especially in light of the recent trend in international law assigning national sovereignty for biodiversity to individual countries (Anonymous, 1992; Commission on Genetic Resources for Food and Agriculture, 2001).

An additional issue is the type of scientific data required to document an invention. Color in the case of the Enola patent was documented by a Munsell Color chart. There are now more modern, accurate, and reproducible ways of documenting color. Likewise, molecular markers provide opportunities to more accurately document differences or similarities (depending on whether one seeks to document ownership or infringement!).

Finally, there is increasing reliance on utility patents to claim ownership over a new cultivar. The U.S. is the only country, with Japan and Australia, in allowing patents for cultivars. Other countries only provide PVP protection based on the UPOV convention. Because PVP offers a breeder's exemption, breeders can use a PVP cultivar as a parent in crosses to develop the next generation of improved cultivars. Utility patents offer no such exemption. This situation raises questions whether the absence of breeder's exemption is going to limit germplasm exchange and progress from breeding will be slowed down as a consequence. Given the 7-10 year time frame, the answer to these questions is not immediately forthcoming. However, in our opinion there has been almost no discussion in the breeding community in general about this issue.

From a broader, international perspective, the increased emphasis on intellectual property rights over crop cultivars, in particular, and biodiversity, in general, raises a number of questions (Gepts 2004), including whether living organisms and any of their constituting parts (including genes) be subject matter of IPRs; whether reliance on IPRs will assure efficient conservation and utilization of biodiversity; whether the non-utilitarian functions of biodiversity, such as ecosystem health and function as well as its esthetic role, well served by a IPR regime; and whether legal and economic frameworks can be instituted that address the conservation of both biological and cultural diversity? Given that the new era of IPR for biodiversity only started some 25 years ago, much needs to be discussed still. Biologists, in general, and breeders, in particular, should be involved.

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