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Item 6.5 of the Draft Provisional Agenda

COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Eleventh Regular Session

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UPDATED INFORMATION PROVIDED BY THE INTERNATIONAL CENTRE FOR TROPICAL AGRICULTURE (CIAT), REGARDING ITS REQUEST FOR A RE-EXAMINATION OF U.S. PATENT NO. 5,894,079

CIAT has made the attached document available, for the information of the Commission in considering agenda item 6.5, *International cross-sectorial policy matters on genetic resources.* The document provides up-dated information on CIAT's request for a re-examination of U.S. Patent No. 5,894,079.

UPDATED INFORMATION PROVIDED BY THE INTERNATIONAL CENTRE FOR TROPICAL AGRICULTURE (CIAT), REGARDING ITS REQUEST FOR A RE-EXAMINATION OF U.S. PATENT NO. 5,894,079

The patent and its claims

As inventor of a new cultivar of field bean (*Phaseolus vulgaris* L.), Mr Larry M. Proctor, owner of POD-NERS L.L.C., was granted in April 1999 U.S. Patent No. 5,894,079 by the United States Patent and Trademark Office (USPTO) filed on 15 November 1996. This bean, named 'Enola', produces a distinctly yellow (sulfur-colored) seed with a yellow hilum (deposited as ATCC 209549). The color remains relatively unchanged through time. The invention also relates to a method for producing a field-bean cultivar by crossing a first parent field-bean plant with a second parent field-bean plant, wherein the first and/or second field-bean plant is that of the invention.

In 1994, field beans with yellow seeds were discovered in a package of dry edible beans purchased in Mexico and brought to the United States. In the same year, the yellow beans were selected from the package of miscellaneous beans, planted, and allowed to self-pollinate. The seeds harvested from this crop were planted in 1995 and also allowed to self-pollinate. The process was repeated for 1996. All three crops (1994, 1995, and 1996) were planted in Montrose County, and the patent requested after the 1996 harvest.

The *Phaseolus* bean collection held at CIAT

By 1996, CIAT had designated 28,393 accessions of *Phaseolus* beans to the Food and Agriculture Organization of the United Nations (FAO). A total of 5,680 accessions was from Mexico, of which 260 were yellow seeded and had vernacular names such as 'Canario' (Canary), 'Amarillo' (Yellow), 'Azufrado' (Sulfur-Colored), and 'Garbancillo' (Little Chickpea) that reflected the beans' color. Six of the bean accessions with sulfur-yellow seeds and hilum and designated to FAO matched the description of 'Enola' as provided in the patent (Hidalgo et al. 1992).

The FAO-CGIAR Agreements

CIAT signed an agreement with FAO on 26 October 1994. This Agreement stipulated that the Center undertakes to make samples of designated germplasm and related information directly available to users or through FAO for purposes of scientific research, plant breeding, or genetic resources conservation without restriction (Art. 9). When samples of the designated germplasm and/or related information are transferred to any other person or institution, the Center shall ensure that such other person or institution, and any further entity receiving samples of the designated germplasm from such person or institution, are bound by the conditions set out in Article 3 (b) (art. 10). Article 3 indicates that the Centre shall not claim legal ownership over the designated germplasm, nor shall it seek any intellectual property rights over that germplasm or related information. This agreement has since been renewed, and on October 16, 2006, CIAT has celebrated an agreement with the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture, by which the in-trust collections namely 35,231 accessions are included into the Multilateral System on Access and Benefit Sharing.

To handle the distribution of designated germplasm, a Material Transfer Agreement was developed in 1995 and, from then on, any sample of designated germplasm was distributed by CIAT's Genetic Resources Unit upon acceptance of the terms stipulated in the Material Transfer

Agreement. Since the adherence to the International Treaty, CIAT now uses the Standard Material Transfer Agreement, namely for the bean collections listed in Annex 1 of the Treaty.

In 1998, FAO and the CGIAR Centers produced a second joint statement. It stated:

> "The Centers recognize that many accessions designated under the Agreements with FAO were distributed to plant breeders and researchers prior to designation in keeping with the CGIAR policy for providing "unrestricted availability" to germplasm – as noted in the preamble of Agreements. In dealing with this situation, the Centers will request and urge that no intellectual property rights be sought for designated germplasm that was distributed before its designation under the FAO-CGIAR Agreement."

CIAT's concerns and reasons for challenging the patent

Patent No. 5,894,079 restricts the use of designated bean germplasm with yellow seeds for purposes of agronomy and breeding in the USA, even though the FAO-CGIAR Agreements expressly prohibit the claiming of intellectual property rights on designated germplasm, even for accessions distributed before their designation (1998 Second Joint Statement).

In addition, the patent does not fulfill two basic requisites: newness, and nonobviousness. That is:

> The yellow colour of the 'Enola' bean seeds is not an invention. It had existed in the Americas since pre-Columbian times, as witnessed by considerable prior documentation or 'prior art' —see, for example, Irish (1901), Bukasov (1930), Hernández (1973), Kaplan (1980), Lépiz & Sandoval (1983), Voysest (1983), Gepts (1988), Hernández et al. (1991), Voysest & Dessert (1991), and Kaplan & Lynch (1999). These works, several of them having been published in the US and accessible to professional bean breeders, are not mentioned in the patent.
>
> The patent does not fully describe the breeding process that gave rise to 'Enola'. However, those details available from the incomplete description suggest that neither is the breeding process a novelty. Again, considerable prior documentation is available on similar breeding processes—see, for example, Fermond (1855), Buishand (1956), Fouilloux (1978), Fouilloux & Bannerot (1988), Singh (1991, 1992), and Beaver & Kelly (1994). These works are not mentioned in the patent. Bassett and co-workers (2002a) in the *Journal of the American Society of Horticultural Science* have provided recent evidence that there is no novelty on the trait nor on the breeding process. Pallotini and co-workers (2004) using AFLP fingerprinting have shown in *Crop Science* the near identity between 'Enola' and the pre-existing improved cultivar 'Azufrado Peruano 87' (released in Mexico in 1988).

On 7 March 2000, the Director General of CIAT wrote a letter to Mr Proctor indicating that the 'Enola' bean is close to several yellow-seeded bean varieties deposited in the intrust collection held at the Center, and that CIAT will continue to distribute freely such germplasm accessions in the framework of the FAO-CGIAR Agreement. CIAT did not receive a reply to this letter.

Current status of the challenge

CIAT challenged the patent on 20 December 2000 by asking for a re-examination through the law offices of Dodds Associates, Washington, DC. On 8 February 2001, the USPTO indicated that it would re-examine the patent and its claims 1 to 15.

On 11 July 2001, the patent owner asked that claims 1 to 15 be cancelled and added claims 16 to 58. CIAT made pertinent searches on these new claims; these were found as continuing to ignore

all the above-cited documentation, and as not fulfilling the basic requirements for patent ownership according to U.S. law.

In November 2001, Constanza Quintero, CIAT-BRU, used microsatellites (a form of molecular marker) to survey 21 bean lines with yellow seeds and hilum. 'Enola' was discovered to be genetically very close to the CIAT accessions G22227 and G14024. G22227 is a INIA breeding line from Sinaloa and Sonora, north western Mexico; and G14024, also known as 'Peruano', a bean line that CIAT obtained from Mexico, but which is originally from Peru (see also Valladolid & Voysest 2006). César Ocampo, CIAT-GRU, showed that 'Enola' has 'T' phaseolin, a marker that is common among wild forms and landraces of the Central Andes of Peru, and also found in 'Peruano' and G22227.

In May 2004, a group of researchers of the University of California-Davis published in *Crop Science* a detailed analysis of various yellow-seeded cultivars with the help of amplified fragment length polymorphisms. Their results showed that 'Enola' was most closely related to the pre-existing Mexican cultivar 'Azufrado Peruano 87'. Their probability calculations of matching the fingerprint of 'Enola' showed that the most likely origin of 'Enola' was by direct selection within pre-existing yellow-seeded cultivars from Mexico, most probably 'Azufrado Peruano 87'.

These findings suggest that the yellow bean purchased in Mexico and from which 'Enola' was developed was already the product of breeding work done in Mexico with originally Peruvian germplasm (similar conclusions were raised independently by Pallotini et al., 2004). The following publications describe this breeding work: Lépiz & Sandoval (1983), Voysest (1983; 2000a; 2000b), and Kelly (2000).

In the *Annual Report of the Bean Improvement Cooperative (USA)* of 2002b, Mark Bassett and co-workers reported about a genetic study of the yellow seed testa in common bean, and concluded (p. 25): "All the above experimental work demonstrates that the claim of the Enola Patent (US Patent No. 5,894,079) to have "invented" the greenish yellow color of 'Enola' is false".

Over the past years, several bean producers in the western states of USA and growing other types of yellow beans have been challenged by POD-NERS in court under the assumption that they were growing 'Enola' without permission. The companies Northern Feed & Bean (of Lucerne L.L.C.) and Yellow River L.L.C., and several farmers and growers are currently attempting to prove in court that various varieties of yellow field beans were a matter of public knowledge before 1996. For instance, the horticultural catalogue of National Gardening (issue of September-October 1992) has printed a color picture of 'Sulphur', indicating this market class of beans has long been present in the United States. As a matter of fact, Kelly (2000) indicated that he planted 'Azufrado Peruano 87' in Michigan in 1992.

In March 2007, the Patent Examiner notified the patent owner that all of the filed claims old and new ones have been rejected (as done in April and December 2005); from a strict re-examination the case evolved into a continuation, e.g. filing of new claims and examination, that made possible for the Examiner to consider publications and recent factual evidence. Having exhausted all appeals possible within the USPTO (three months and six months appeals), the patent owner would appeal to the next step, the Board of Patent Appeals and Interferences, where a decision might be made within the next semester.

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