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Organización  
de las  
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para la  
Agricultura  
y la  
Alimentación

## COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

**Second meeting of the Commission on Genetic Resources for Food and  
Agriculture acting as Interim Committee for the International Treaty  
on Plant Genetic Resources for Food and Agriculture**

**Rome, 15 – 19 November 2004**

**Preliminary report on work towards the assessment of patent data  
relevant to availability and use of material from the International  
Network of *Ex-Situ* Collections under the Auspices of FAO and the  
International Treaty on Plant Genetic for Food and Agriculture  
(ITPGR)**

This study responds to the request from the Ninth Session of the Commission, that the World Intellectual Property Organization (WIPO) should “cooperate with FAO in preparing a study on how intellectual property rights may affect the availability and use of material from the International Network [of *Ex-Situ* Collections under the Auspices of FAO] and the International Treaty [on Plant Genetic Resources for Food and Agriculture].”

It provides a report on the preliminary work that has been undertaken towards an assessment of patent data relevant to the use of these materials.

For reasons of economy, this document is produced in a limited number of copies. Delegates and observers are kindly requested to bring it to the meetings and to refrain from asking for additional copies, unless strictly indispensable.  
Most FAO meeting documents are available on Internet at [www.fao.org](http://www.fao.org)

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## I. EXECUTIVE SUMMARY

1. This paper provides an interim first response to the request of the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA) “that WIPO cooperate with FAO in preparing a study on how intellectual property rights may affect the availability and use of material from the International Network and the International Treaty.”<sup>1</sup> It sets out the background of this request; its legal and policy contexts; the methods used to provide preliminary, illustrative information; the limitations on conclusions that can be drawn from such information; and options for possible follow-up activities.

2. To commence work towards a survey of the issues, this interim paper only considers patents, rather than intellectual property more generally. Overall, the question of the effects on availability and use of material needs to be considered from legal, practical and policy perspectives. One initial pathway to gaining insights on this question is to build up an information base on relevant patents and patent applications. To initiate this process, using existing patent search algorithms, a few sample searches were conducted in order to test the methods and broadly illustrate the type of information that could be generated for the CGRFA, and on that basis to pose questions about how such information could be refined and used to clarify understanding about the effects on availability and use.

3. The main insights from these preliminary sample searches is to illustrate the choices involved in developing a search method, and the *type* of raw data that might be obtained through its use. Above all, it illustrates the limitations of the conclusions that can be drawn from broad-brush patent searching, and underscores the need for careful analysis of the content, scope and implications of specific patents before any substantive assessments can be made. This preliminary report is not intended to be, and cannot constitute, opinions or guidance concerning patent infringement or validity. Beyond illustrative purposes the data provide, at most, a rough indication of broad patenting activity over time in relation to the general industrial and technological potential of the individual crops and forages, including many forms of industrial use of these crops and extracts of crops altogether beyond the ambit of the Commission’s work. On the basis of these searches, few patents disclosed directly claim PGRFA as such, and many more deal with technologies potentially used for the transgenic transformation of such crops. The document ends by identifying options for follow-up activities, based on the initial insights yielded by these searches. Above all, this exercise has illustrated the need for more extensive examination of the patent landscape, and the broader legal context, that surrounds particular crops, before any practical assessment can be made about the effect on availability and use of material that may be covered by patents. It is clear that no substantive conclusions can or should be drawn from these basic data, and these data are unlikely to yield overall insights on availability or non-availability of material. The document ends by identifying options for follow-up activities, based on existing collaboration between FAO and WIPO. The sample patent searches were conducted by the Institute for Genome Sciences and Policy at Duke University, Durham, North Carolina, USA, and this contribution is gratefully acknowledged.

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<sup>1</sup> See, *Report of the Commission on Genetic Resources for Food and Agriculture*, Ninth Regular Session, Rome, 14-18 October 2002 (para. 31, CGRFA-9/02/REP).

## II. INTRODUCTION AND BACKGROUND

4. At its ninth session, the CGRFA considered a ‘Report on the International Network of *Ex Situ* Collections under the Auspices of FAO.’<sup>2</sup> Following discussions on this Report, the CGRFA “requested the Director-General of FAO to bring the matter to the attention of the United Nations General Assembly and the World Trade Organization, and to forward the documents, *Report on the International Network of Ex Situ Collections under the Auspices of FAO* and *Report on the International Network of Ex Situ Collections under the Auspices of FAO: further information provided by CIAT, regarding a request for the re-examination of US Patent No. 5,894,079*, to the World Intellectual Property Organization (WIPO) and its various Committees, with a request that WIPO cooperate with FAO in preparing a study on how intellectual property rights may affect the availability and use of material from the International Network and the International Treaty.”<sup>3</sup>

5. Following this request by the CGRFA, the FAO and WIPO Secretariats have worked together to consider how they could best cooperate to study effects that IP rights might have on the availability and use of material from the International Network and the International Treaty. These discussions identified a preliminary need for more factual information on global patenting trends pertaining to the crops included in the International Network and the multilateral system of the International Treaty, and for a clearer factual and conceptual framework for analyzing and exploring the implications of those trends. This paper seeks to set out ways in which this need could be met, beginning with the policy and legal context in which the need arises.

6. In addition, the work of the CGRFA on this matter has also provided input for the work of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC) on defensive protection of genetic resources, in other words the development of tools and strategies to reduce the likelihood that patents are granted over subject matter that does not meet the criteria for patentability, in particular novelty and inventive step (see, for example, WIPO document WIPO/GRTKF/IC/6/5). This illustrates how information on plant genetic resources, such as that assembled in the IPGRI SINGER database, may be of use within the patent system to ensure that a broad scope of relevant prior art is taken into account during patent search and examination. An enhanced information flow could therefore operate in two directions: further information about existing plant genetic resources could flow from the international network into the patent search and examination process, helping to focus this process onto the valid aspects of patent claims; and improved information about the nature, scope and status of relevant patents and the overall patent landscape may assist in understanding the effects on availability and use of plant genetic resources in line with the request of the Commission.

## III. POLICY AND LEGAL CONTEXT

7. The Study which the CGRFA requested should address “how intellectual property rights may affect the availability and use of material from the International Network and the International Treaty.” Three policy and legal contexts are therefore of immediate relevance to the study: (1) the International Network of *Ex Situ* Collections under the Auspices of FAO; (2) the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR); and (3) intellectual property systems established under applicable national laws, in particular, patents national and regional patent systems. This section provides a short introduction to each of these policy and legal contexts.

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<sup>2</sup> See, *Report on the International Network of Ex situ Collections under the Auspices of FAO* (Ninth Regular Session, Rome, 14-18 October 2002 (paras 23 to 26, CGRFA-9/02/11).

<sup>3</sup> See, *Report of the Commission on Genetic Resources for Food and Agriculture*, Ninth Regular Session, Rome, 14-18 October 2002 (para. 31, CGRFA-9/02/REP).

### 3.1 *International Network of Ex Situ Collections under the Auspices of the FAO*

8. In 1989 the CGRFA called for the development of the International Network of *Ex Situ* Collections under the Auspices of FAO, in line with Article 7.1(a)<sup>4</sup> of the International Undertaking on Plant Genetic Resources,<sup>5</sup> because of a lack of clarity regarding the legal situation of the *ex situ* collections. Twelve centres of the Consultative Group on International Agricultural Research (CGIAR) signed agreements with FAO in 1994, placing most of their collections (some 500,000 accessions) in the International Network. Through these agreements, the Centres recognised the “intergovernmental authority of FAO and its Commission in setting policies for the International Network.” They have agreed to hold the designated germplasm “in trust for the benefit of the international community,” and “not to claim ownership, or seek intellectual property rights, over the designated germplasm and related information.” The Regional Collection of the International Coconut Genetic Resources Network (COGENT), held by the governments of India, Indonesia and Cote d'Ivoire have also, since October 1998, been brought into the Network. The CGRFA monitors the implementation of the agreements and the Centers of CGIAR are invited to report to its biennial sessions. The CGRFA had stated that the Agreement provides an interim solution, until the International Undertaking had been revised. Article 11.5 of the binding international instrument resulting from that revision, the ITPGR, provides that “the Multilateral System [established by Part III of the ITPGR] shall also include the plant genetic resources for food and agriculture listed in Annex I and held in the *ex situ* collections of the International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR)” The CGRFA, at its present session, has been invited to “provide guidance for the further development of the components of the FAO Global System, in the light of the coming into force of the International Treaty” and to “invite the Governing Body of the International Treaty to propose ways in which the Governing Body and the Commission may establish a cooperative framework in order to develop the relevant components of the FAO Global System.”<sup>6</sup> Consequently, the next sub-section provides a brief reference to the main provisions of the ITPGR which are relevant to these searches.

### 3.2 *The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR)*

9. Part IV of the International Treaty establishes a Multilateral System of Access and Benefit-sharing which covers all PGRFA listed in Annex I of the Treaty.<sup>7</sup> However, not all plant genetic resources of crops on Annex I are included in the Multilateral System. Only those plant genetic resources listed in Annex I “that are under the management and control of

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<sup>4</sup> Article 7.1(a), IU, reads as follows: “The present international arrangements, being carried out under the auspices of FAO and other organizations in the United Nations System, by national and regional institutions and institutions supported by the CGIAR, in particular the IBPGR, for the exploration, collection, conservation, maintenance, evaluation, documentation, exchange and use of plant genetic resources will be further developed and, where necessary, complemented in order to develop a global system so as to ensure that: (a) there develops an internationally coordinated network of national, regional and international centres, including an international network of base collections in gene banks, under the auspices or the jurisdiction of FAO, that have assumed the responsibility to hold, for the benefit of the international community and on the principle of unrestricted exchange, base or active collections of the plant genetic resources of particular plant species.” (Emphasis added)

<sup>5</sup> Available online at <<http://www.fao.org/ag/cgrfa/IU.htm>>

<sup>6</sup> See, CGRFA. *Overview of the FAO Global System for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture and its Potential Contribution to the Implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture*, Tenth Regular Session, Rome, November 8 to 12, 2004, paras 33 and 34).

<sup>7</sup> Article 11.1 ITPGR.

the Contracting Parties *and in the public domain*” are included within the Multilateral System.<sup>8</sup> No attempt is made here to interpret this treaty provision, but when a PGRFA is directly covered by the claims of a national or regional patent that is in force in the relevant jurisdiction, it would in normal usage not be considered to be in the public domain within that jurisdiction, until the patent term has expired or the patent has lapsed, although this would not apply in jurisdictions where the patent was not in force. Accurate information about the patenting landscape in relation to the PGRFA listed in Annex I and covered by the Multilateral System might assist the CGRFA in basing its policy decisions on a more detailed understanding of the difference between material which is covered in the Multilateral System and material which is included in the Multilateral System at a given time. The Multilateral System also includes PGRFA which are listed in Annex I and held by the Centres of the CGIAR, or by other entities that have voluntarily included them in the Multilateral System.<sup>9</sup> Facilitated access to PGRFA in the Multilateral System is to be accorded through a standard Material Transfer Agreement (MTA) to be adopted by the Governing Body of the International Treaty.

10. Article 13 of the International Treaty sets out the agreed terms for benefit-sharing within the Multilateral System. Mechanisms for benefit-sharing include the exchange of information, access to and transfer of technology, capacity building, and the sharing of benefits arising from commercialisation.<sup>10</sup> The standard MTA is to include a requirement for recipients that commercialize products that are PGRFA and incorporate materials accessed from the Multilateral System to pay an equitable share of the benefits arising from the commercialisation of the product to an international fund or other mechanism established by the Governing Body.<sup>11</sup> This payment is mandatory where restrictions are placed on the availability of the product for further research and breeding. This situation may arise, for example, where a patent is in force that has a claim covering such a product (a commercialized product incorporating accessed materials): depending on the relevant national patent law and the exceptions that apply, this may mean the product/PGRFA is considered not to be available for further research and breeding without restrictions; this would depend also on the nature of the relevant claims. Further information about patenting trends in relation to PGRFA listed in Annex I, coupled with a review of relevant patent law issues, might assist in gaining an indirect understanding of the amount of PGRFA for which the Treaty’s provisions on sharing of monetary and other benefits from commercialization might become relevant. In some jurisdictions, the grant of a patent may not restrict further research on a PGRFA (depending also on the nature of claims). In cases where no restrictions are placed on further availability for research and breeding, the recipient is not under any obligation to make such a payment, but is encouraged to do so. It is important to note, however, that searches do not address technological or contractual restrictions to further research and plant breeding for PGRFA from the Multilateral System. In particular, the patent searches give no information about any licenses for use of the patented inventions, or provisions contained in such licenses. In their current form, the searches do not give any indication even as to whether patents are still in force, or have lapsed (many patents lapse before their full theoretical term). Another scenario that may arise is when a relevant patent right is waived by the patent holder to permit research and breeding. Accordingly, other potentially relevant considerations include the manner in which patent rights are exercised, including the implication of voluntary waiving of rights over research and breeding. No patent search will shed light on issues of this nature.

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<sup>8</sup> Article 11.2 ITPGR. Emphasis added.

<sup>9</sup> Article 11.5 ITPGR.

<sup>10</sup> Article 13.2 ITPGR.

<sup>11</sup> Article 13.2(d) ITPGR.

11. Finally, Article 12 sets out the terms and conditions that will be applicable for such facilitated access. These include that recipients of material through the Multilateral System are required not to claim intellectual property rights, including patent rights, that limit facilitated access to PGRFA, or their genetic parts or components in the form received from the Multilateral System. Defensive protection mechanisms may be relevant to this provision, including measures to improve the practical availability of information on PGRFA that would be relevant prior art, and disclosure mechanisms relevant to genetic resources (see for example WIPO documents WIPO/GRTKF/IC/5/6 and WIPO/GRTKF/IC/6/5).

### **3.3 *Patent law, policy and information systems***

12. A patent gives a right to exclude third parties from making, using or selling a claimed invention for as long as the patent remains in force (this right is subject to certain exceptions); if a patent claim includes in its scope a PGRFA, this may, accordingly, place a limitation on others' use of that resource. National laws differ on patentable subject matter and, as a result, some PGRFA may be ineligible for patent protection in some countries, even if they meet all other criteria for patentability. This is a matter of considerable debate internationally, and no attempt is made in this document to set out the issues and processes concerned. It should be noted, however, that practically, under current conditions, even if a patent in one country covers PGRFA, it may not be eligible for patent protection in other countries. In addition, the actual scope of claims granted may differ from country to country, owing to differences in law and practice.

13. Patents are generally granted, administered and enforced under national law. Some regional systems do provide for the grant of a regional patent (to be enforced ultimately under national law), but there is no international patent as such (the Patent Cooperation Treaty, briefly described below, does provide for an international system that facilitates the patent application process). Patents have effect only in the jurisdiction for which they are granted. Accordingly, any patent that is relevant to availability and use of PGRFA can only legally affect that availability or use in the jurisdiction in which it is in force. Even where a certain PGRFA falls within the scope of an invention patented in one country, this PGRFA would be considered legally in the public domain in any country where a corresponding patent was lacking (barring any other constraints, including other applicable patents). Under current international standards, a patent should be available for at least twenty years from the filing of the patent application. In practice, however, many patents lapse prior to the expiry of this full twenty-year term. Many patent applications also are refused or lapse without a patent being granted at all; often, the claims in an application are modified and narrowed during the examination process. Accordingly, even if a patent application is located in a search, this does not mean that an enforceable patent right will be granted; and, if a patent is granted, it may be subject to narrower claims than are drafted in the original application. Close attention to the legal status of a patent document, the territorial jurisdiction it applies to, and the scope of actual granted claims, is therefore required before making an assessment as to its impact on availability or use of PGRFA.

14. Patents in different jurisdictions are independent of one another: so, in principle, whether or not a patent is valid or is in force in one country doesn't affect the legal status of a corresponding patent in another country. But one important linkage is that of 'priority date.' After a patent application has first been filed, subsequent applications for protection of the same invention filed in other countries (up to 12 months later) can 'claim priority' from this original and receive as their 'priority date' the date of filing of the first application. This means that they are considered to have been filed on the priority date when considering such issues as whether the invention is novel and inventive, for instance. The Patent Cooperation Treaty (PCT) system provides an international application process that preserves 'priority' in many national and some regional systems, based on a single international patent application. It is an international application process: it does not lead to an international patent, but precedes entry

into existing national or regional patent procedures. A booklet on basic facts about the PCT is available at [http://www.wipo.int/pct/en/basic\\_facts/basic\\_facts.pdf](http://www.wipo.int/pct/en/basic_facts/basic_facts.pdf). Once the ‘international phase’ is over, PCT applications are dealt with as national or regional applications and their legal effect is no different from non-PCT applications filed in the regular way with the national or regional patent authorities. The PCT system includes a searchable database of international patent applications and search reports which was used in part for this study.

15. The concept of ‘priority’ is also an important practical tool in searching for relevant patents and patent applications in different jurisdictions. A patent ‘family’ is a set of national and regional patents filed in different jurisdictions in respect of the same invention, originating from the same inventor(s). They are normally united by the one ‘priority document,’ the first patent application filed in respect of this invention. When considering the international patent landscape, developing an understanding of the scope of relevant patent families is an important factor because individual patents are relevant only to use and accessibility of material in one jurisdiction (or regional collection of jurisdictions) alone.

#### **IV. OBJECTIVES AND SCOPE OF THE SAMPLE SEARCHES**

16. In light of the legal and policy context set out above, the sample searches in Section 7 seek to illustrate the issues that arise in seeking to draw linkages between the patent system and the access and use of genetic material covered by the International Network and the International Treaty. Ideally, further information and analysis may be able to contribute to:

- a better understanding of the effects of patent activity on the availability of genetic material from the International Network of *Ex Situ* Collections;
- a general approximation of the overall scale of situations in which patents create implications for access to PGRFA on Annex I could be restricted for research and breeding. This may help in identifying the broad order of magnitude of the numbers of patents that may be relevant to Article 13.2(d)(ii) ITPGR and could fall under the commercial benefit-sharing provisions of the Treaty;
- a general understanding of how to assess the scale of Annex I crops that might be considered not to be in the public domain in different jurisdictions. This might assist in distinguishing between those PGRFA of Annex I crops which are merely covered by the Multilateral System and those which are also included in the Multilateral System (i.e., relevant to Article 11.2 of the Treaty);

17. If the information generated by the searches were to shed light on these questions, the scope and coverage of the searches would ideally include:

- patents which directly claim PGRFA included in the International Network and (following its establishment) the multilateral system of the International Treaty; patents which directly claim genetic elements derived from such PGRFA;
- patents that relate to products for commercialization that incorporate PGRFA, including those that appear not to be relevant to the International Treaty;
- no patents which relate to PGRFA, but do not claim genetic material from the patents (e.g., machinery for canning corn or planting rice, etc);
- the jurisdictions of those countries which participate in the International Network and/or have become Contracting Parties to the International Treaty.

It should be noted that a number of these issues entail interpretation of the International Treaty (for example, the forms of ‘use’ that are relevant), and that any patent search and analysis of data should not pre-empt or express a position on questions of interpretation.

18. It needs to be stated clearly that, at the present state of FAO/WIPO work, the sample searches, which are contained in this paper for illustrative purposes only, do *not* provide such

coverage and therefore do *not* allow for concrete conclusions on the three questions set out above. The reasons for this are elaborated in detail in Sections 6 and 8 below. The sample searches are, at this stage, not intended to provide answers to the questions listed above, but merely to illustrate the methodology that could be used to start a process to narrow down the range of patents that might be relevant to these issues, the kinds of results it could produce, and the further work that might be required. The next chapter sets out the method used to develop this initial data set.

## V. METHODS

19. The preliminary method used for the sample searches was based on the objectives and scope of the searches, and the nature of the request issued from the CGRFA. At this early stage in the work, it was the method itself, which formed the primary object of study - more so than the preliminary data that it generated.

### 5.1 *Method used for sample searches*

20. The method is described here in several stages, namely: selection and short-listing of key crops; selection of patent databases to be used; development of a preliminary search algorithm through adaptation of existing algorithms for DNA-based patents; conduct of the searches; and limitations on their interpretation.

#### 5.1.1 *Selection and short-list of crops*

21. As an initial step, FAO and WIPO selected, with the assistance of the International Plant Genetic Resources Institute (IPGRI),<sup>12</sup> a few key crops for the conduct of the sample searches. FAO and WIPO selected small crops in order to limit the initial costs and datasets of the sample searches. Among the small crops included in the International Network and the multilateral system of the International Treaty the selection criteria were the importance of the crop for food security in different regions, the amount of research and development occurring in relation to the respective crop, and the distribution of such activity in different regions. For contrast, one crop (groundnut) was included which is not on Annex I of the Treaty. Based on these selection criteria, FAO and WIPO arrived at the following shortlist of crops for the sample searches: banana/plantain, beans, cassava, groundnut, and millet.

#### 5.1.2 *Patent databases used*

22. The primary database used for the sample searches was the Delphion Patent Database by Thomson. Some issues that may determine future choice of databases include coverage of relevant jurisdictions, including those of developing countries, capacity to search within patent claims, ease of use, reliability of patent family designations, currency of the database, and consistency of responses to inquiries. Other factors that would be needed to make more sophisticated judgments about freedom to operate in relation to covered crops would include the legal status of the patents (including whether they are still in force or have lapsed, and whether they are subject to challenge, opposition or office proceedings such as re-examination).

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<sup>12</sup> WIPO wishes to thank Mrs. Susan Bragdon and Prof. Cary Fowler, both at the time at IPGRI, for their assistance in the selection of crops for the sample searches.

### 5.1.3 Preliminary search algorithm

#### 5.1.3.1 Based on pre-existing algorithms

23. The preliminary search algorithm used for the sample searches in Section 7 was based on the Ade/Cook-Deegan algorithm,<sup>13</sup> which was in turn developed from the original Martinell algorithm in 1993.<sup>14</sup> The Martinell algorithm was developed in response to a request from the Office of Technology Assessment of the Congress of the United States of America, by Senior Examiner James Martinell of the United States Patent and Trademark Office (USPTO). Both algorithms were used to conduct specialized searches for patents over genetic materials in other fields of technology. The preliminary algorithm used in the present paper to generate the sample data was based on, and developed through, a systematic modification of these pre-existing algorithms by members of the same team which developed the Ade/Cook-Deegan algorithm.

24. The ‘algorithms’ are essentially search filters, which narrow down the full range of patents or patent applications according to two general criteria:

- basic subject matter of the patent, as defined by the standard classifications used (the national US Patent Classification, and the International Patent Classification, as appropriate).
- the presence of one or more key terms in the claim or claims of the patent (the claims are a distinct portion of a patent document that explicitly spell out the precise scope of the invention that is the basis of the exclusive claim); this is distinct from a regular ‘full text’ search that would disclose any patent that mentioned, for example, the word ‘cassava’ in any part of the description of the invention or the background to the invention.

While the focus on the claims as such provides some precision, such a search technique will not discriminate between, for example, a patent that claims a new cassava plant altogether as the invention (where this is permitted subject matter), and a patent that claims an invention which is a new method of preserving harvested cassava (along with many other crops) for transportation, or a new method of creating a transgenic plant, which may be cassava along with many other crops.

<sup>13</sup> The Ade/Cook-Deegan algorithm reads as follows:

“(047??\* OR 119\* OR 260??\* OR 426\* OR 435\* OR 514\* OR 536022\* OR 5360231 OR 536024\* OR 536025\* OR 800\*) <in> NC) AND ((antisense OR <case><wildcard>cDNA\* OR centromere OR deoxyoligonucleotide OR deoxyribonucleic OR deoxyribonucleotide OR <case><wildcard>DNA\* OR exon OR "gene" OR "genes" OR genetic OR genome OR genomic OR genotype OR haplotype OR intron OR <case><wildcard>mtDNA\* OR nucleic OR nucleotide OR oligonucleotide OR oligodeoxynucleotide OR oligoribonucleotide OR plasmid OR polymorphism OR polynucleotide OR polyribonucleotide OR ribonucleotide OR ribonucleic OR "recombinant DNA" OR <case><wildcard>RNA\* OR <case><wildcard>mRNA\* OR <case><wildcard>rRNA\* OR <case><wildcard>siRNA\* OR <case><wildcard>snRNA\* OR <case><wildcard>tRNA\* OR ribonucleoprotein OR <case><wildcard>hnRNP\* OR <case><wildcard>snRNP\* OR <case><wildcard>SNP\*) <in> CLAIMS)”

Online at <<http://dnapatents.georgetown.edu/SearchAlgorithm-Delphion-20030512.htm>>

<sup>14</sup> The Martinell algorithm reads as follows:

“(435\* OR 800\* OR 530\* OR 536/23\*) <in> NC) AND ((sequenc\* OR (atga\* OR atgc\* OR atgg\* OR atgt\*) OR cDNA? OR deoxyribo\* OR deoxynuclei\* OR deoxynucle\* OR dna? OR gene? OR nucle\* OR nucleotide OR oligonucle\* OR oligodeoxy\*) <in> CLAIMS)”.

### 5.1.3.2 Modification of preexisting algorithms

25. The pre-existing algorithms (Ade/Cook-Deegan and Martinell) were modified for the sample searches in Section 7. The modification entailed simply retaining the same US Patent Classification classes (and their IPC equivalents, as appropriate), but altering the strings of search terms. Instead of the DNA-related terminology used in the original algorithms, the terms used related to the crops themselves, including various common names and botanical names. The changed search terms were based *inter alia* on terminology sheets relating the botanical names of the short-listed crops which were provided by the FAO and IPGRI. For an example of the terminology sheets provided for the selected crops by FAO and IPGRI see the sheet for “phaseolus/beans.” These were provided to the patent searching team for their perusal in the searches.

26. After the searches were completed, specificity testing was done with the result sets through spot checks to identify the ‘false positive’ rate (i.e., patents captured by the algorithm that should not be). Such specificity testing of the algorithm ascertains whether it produces *only* those patents which should be contained in the result sets and not patents lacking DNA- or RNA-based claims or not pertaining to the species subject of the search. This was done through spot checking and ‘light weeding’ of the result sets. Some patents initially captured by the algorithm were therefore deleted after screening the titles. Even though it was desirable, limited time and resources did not allow testing of the result sets for sensitivity (false negative rate—or patents that are not captured but should be). Testing for sensitivity requires having a patent set known to be of the type desired, then ensuring that the algorithm captures all those patents. No such set of patents was available at the time of the searches, so sensitivity testing was not possible.

27. There was a number of false positive patents in the spot checks. In most searches, the algorithm incorporated species names in addition to genus, but to use them in tandem (only if both terms are present) would be too restrictive and invites clerical errors leading to missed patents. When initial spot checks revealed few false positives, the simpler strategy of searching for genus generally prevailed. This means the hemp species are also included, for example, with banana cultivated for fruit. Separating these would likely be easier done by reading titles and claims by hand, however, rather than trying to do it by a search strategy, given that the patent counts are not very high.

### 5.1.3.3 The preliminary algorithm

28. The preliminary algorithm resulting from this modification was used to generate the sample data in Section 7. Its elements are as follows in relation to United States patent data (a similar approach was used for other searches, but using the relevant classes in the International Patent Classification):

- first, search US Patent Classes 047 (plant husbandry), 119 (animal husbandry), 260 (organic chemistry), 426 (food), 435 (molecular biology and microbiology), 514 (drug, bio-affecting and body treating compositions), 536/subclasses 22 through 23.1 (nucleic acids, genes, etc., but not peptides or proteins), subclasses 24 and 25 (various nucleic acids, variants, and related methods), and class 800 (multicellular organisms);
- then, select patents from that group that include in the claims one or more of the terms listed in the terminology sheets.

#### 5.1.4 *Sample searches and result sets*

28. The Delphion Patent Database was used.<sup>15</sup> The full result sets have been saved and are available for any further analysis that may be required. These result sets could also be made available on the Internet, if required. If such collections were desired, simple extraction software might be adapted from the DNA Patent Database to create searchable sets of patents for further analysis.

#### 5.1.5 *Limitations on interpretation of preliminary result sets*

29. While these searches may give a very broad indication of general patenting activity over time in relation to the different crops, it does not yet allow for any conclusions regarding possible effects of patenting activity on the availability of the material. This is because of several limitations on the current preliminary search methodology and sample searches, which are described in Section 6 and which could not be further developed due to time and resource constraints. A number of improvements would need to be made to the search methodology and scope, in order to produce reliable searches for a factual understanding of possible effects of patenting activity on the availability of genetic material from the International Network and the International Treaty. Certain possible improvements which could, subject to available resources, be made in the search methodology are described in the next section. In addition, the choice of crops may need to be expanded for a fuller picture.

### 5.2 **Suggested options for refinement and future searches**

30. The preliminary methodology used for the present paper could be improved as follows in order to provide more guidance on general patenting trends relevant to genetic material from the International Network and the International Treaty:

#### 5.2.1 *Improvement of the search algorithms*

31. Normally, a search algorithm is developed and fine-tuned by testing and adjusting both its ‘specificity’ (whether it identifies *only* those patents which it should identify) *and* its ‘sensitivity’ (whether it identifies *all* the patents it should identify). While some preliminary specificity tests were done for the sample searches in Section 7, the most important methodological improvement for the full searches would be to conduct thorough ‘sensitivity testing’ of the search algorithm and some additional, more detailed specificity testing. The starting point for testing sensitivity and specificity is normally a set of patents previously read and coded by hand, or a collection of patents known to be of the type being sought. This would need to be done by an expert with knowledge in the technology as well as in the reading of patent claims.

32. In the past, the Delphion search results were compared to the searches of a similar type on the USPTO’s EAST and WEST software (searches performed on site at the USPTO) for replicability before finalizing the searches on the Delphion search system.

#### 5.2.2 *Increasing scope and coverage of the searches*

33. The sample searches in Section 7 were deliberately restrained to a limited scope and coverage, since they were intended only as illustrations of the methods to be employed and the type of data that might be generated. Possible future improvement to the searches could thus include:

- conducting searches on a larger number of crops,

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<sup>15</sup> Available online at: [www.delphion.com](http://www.delphion.com).

- conducting searches on patent data in languages other than English,
- ensuring a broader coverage of jurisdictions, including searching for all jurisdictions in which it is possible to conduct claims-based searches (in contrast to the kinds of searches that cover the general text of a patent without allowing the searcher to specify the patent claims only, or searches of the abstract and title only of patents),
- where claim searching is not possible, use of the abstract and title as an initial means of locating relevant patents, for subsequent manual filtering (the relatively smaller number of patents in some developing country jurisdictions may make this a practical possibility),
- and narrowing the range of subject matter classifications to those likely to include PGRFA *as such*, as opposed to inventions that use various crops in broader industrial applications.

### 5.2.3 *Information on scope of patent rights in different jurisdictions*

34. While the searches provide an indication of differences in the number of the patent applications filed or the patent titles granted in different jurisdictions, it is also important to take into account differences in the scope and limitation of rights conferred by a patent title in the different jurisdictions. This is important in order to understand the implications of the patent activity for the availability of genetic material for further research. Further understanding of the implications of patents would be worthwhile to supplement the result sets from the searches with complementary information on:

- the different scope patentable subject matter in the different jurisdictions, since this may directly affect the availability of patents for inventions that include PGRFA within their claimed scope;
- the scope and exceptions of rights conferred by a patent in the different jurisdictions, e.g., in particular exceptions to patent rights that may apply to research and breeding, and the scope of so-called ‘reach through’ claims that apply to derivative products created using, for example, a research tool or genetic transformation technology.

This information would provide a basis for making assessments as to the actual impact of specific patents. Such assessments would require selecting patents and reading the claims, entailing expertise in reading and interpreting patent claims in the relevant jurisdictions (as not merely the formal law and the specified scope of patentable subject matter differ between jurisdictions, but also the approach to interpreting the scope of claims).

## **VI. DISCLAIMERS REGARDING RESULTS FROM SAMPLE SEARCHES**

35. Using this preliminary methodology, a few sample searches were conducted in order to test the methodology and broadly illustrate the type of information that could be generated. When reviewing the sample data and querying what it can tell us about the degree to which patents may affect the availability of material from the International Network or the International Treaty, it is important to emphasize that, at the current stage of the work, these preliminary sample searches give no substantive guidance on the availability of genetic material from the selected crops. Many patents disclosed by the search would have no impact on availability, even in the jurisdictions where they are in force. In other cases, it depends critically on specific patent claims and how patents have been licensed. The numbers of patents or patent applications counted should not be taken even as a rough measure of the likely number of relevant patents. At most, the numbers could reveal broad trends in the general commercial, industrial and agricultural use of the plant resources under consideration, within the domain of agriculture and agricultural research and breeding, but also in applications well beyond that field.

36. The main function of these preliminary sample searches is merely to illustrate the factors to be weighed in developing a search method, and in assessing realistically the *type* and potential use of data that might be obtained. Beyond such illustrative purposes the data provide, at most, a rough indication of general patenting activity over time in relation to the individual crops and forages. This Section therefore contains a number of important disclaimers on the coverage, specificity, sensitivity and representativeness of the sample data generated through the searches in Section 7. Any more precise, comprehensive and reliable data would have to be done through the additional steps of specificity and sensitivity testing, and even more importantly, reading and interpreting patent claims, as noted in Section 6.

37. The following important disclaimers must therefore be recognized, before reviewing the data contained in Section 7:

- These are mere patent counts. It is not possible to infer any effects of patenting activity on the availability of genetic material without further research, as described in Section 8 and 9 below. At their present stage of development, these counts are merely rough indicators of patent activity over time in relation to individual crops and forages. Moreover, many of the inventions claimed have no relevance to the work of the CGRFA, and may relate rather to other commercial and industrial applications (for example, in the cosmetics industry);
- These sample searches are based on the search terms of the selected crops, using, where possible, the terminology tables provided by FAO and IPGRI *in the claims of US patents only*. The coverage of other jurisdictions in the search engines and data sets of existing databases do not allow the searcher to restrict the search to claims only, so the search may attract more spurious result sets (i.e., “false positives”). For example, the result sets on Musa in the European searches included some “banana-shaped” and some “banana display case” inventions that were culled out by hand, following spot checks. However, there were not many such cases found in the spot checks;
- Species names were also used in addition to genus. Using them in tandem (including only patents that contain both terms) would have been too restrictive and would have invited clerical errors leading to missed patents. It appeared from early searches like there were not many false positives, so the simpler strategy prevailed. This means the hemp species are also included with banana cultivated for fruit;
- What could not be firmly validated in the initial sample searches was whether they missed some patents that should have been covered through the searches (i.e., confirming the full sensitivity of the searches). To confirm the sensitivity for example of the Musa searches, for example, it would be necessary to begin the sensitivity testing with a known right holder of Musa patents whose patents could be checked to see if they have all been found through the sample searches. This would ideally be a patent holder who is unlikely to have any other kinds of patents, or it could be done if prior analysis in litigation or patent landscape analysis had already identified an exhaustive patent set. In some cases, such an institution may not exist and prior analysis to identify an exhaustive patent collection may not have been performed. Absent such a pre-existing set, it is possible to test the specificity of the searches as has been done in a preliminary way by spot checks (identifying false positives), but one cannot fully validate the *sensitivity* of the searches (identifying false negatives, i.e. how many patents should be found but are missed);
- The US patent classifications (but *not* the specific search terms) used for the sample searches are the ones that were used for the DNA Patent Database of Georgetown University’s Kennedy Institute of Ethics. This approach errs on the side of inclusiveness, since it is an “or” framework. Based on verification of patents in earlier projects, it includes the codes that had patents on biotechnologies, including agricultural patents. We

excluded some classes that would include things like display cases and machinery that handles bananas (but these are not excluded from the European searches - hence the patents that had to be ejected from the European searches by spot checking);

- The seamless coverage of the data sets produced by the patent searches is as extensive or limited as the patent database(s) in which the searches are conducted. The Database in which these searches were conducted, has a range of limitations and therefore the data sets are equally limited to the coverages which are specified in the next section.

## VII. SAMPLE SEARCHES AND PRELIMINARY RESULTS

38. The sample searches of banana/plantain, beans, cassava, cowpea, groundnut and millet were conducted by the Institute for Genome Sciences and Policy (IGSP) at Duke University.<sup>16</sup> IGSP is a university-wide, cross-disciplinary initiative at Duke University dedicated to promoting socially beneficial and ethically responsible uses of genome science and to enhancing the quality of public deliberation about the genomics revolution.<sup>17</sup>

### 7.1 *Qualifications regarding display of preliminary data sets*

39. For ease of reference they are summarized here in graphic form. It is important to recognize, however, that these graphs combine different types of data, which must be carefully and consistently distinguished:

- the graphs labelled 'WIPO PCT' concern international *applications* under the PCT, whereas the European, German, and US patent graphs, refer to *granted* patent titles;
- the PCT applications may subsequently enter into the national phase, and may lead to multiple national patents being granted.

40. The data sets resulting from these sample searches are included in this Section for illustrative purposes only and do not purport to fully and accurately represent all patenting activity related to the crops. Thus, in addition to the disclaimers set out in Section 6 above, the following limitations apply to these specific searches, based on the data coverage of the Delphion database in which they were conducted:

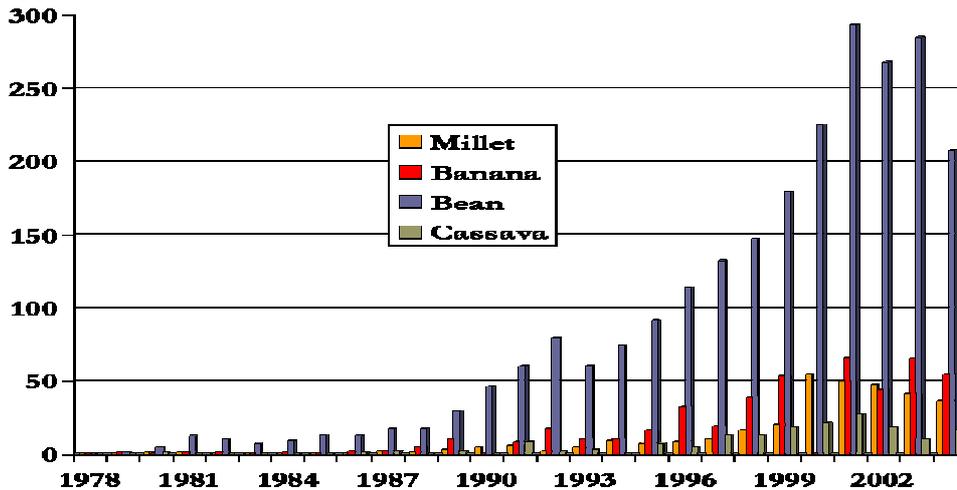
### 7.2 *Preliminary data sets resulting from sample searches*

#### **Overview of international patent applications**

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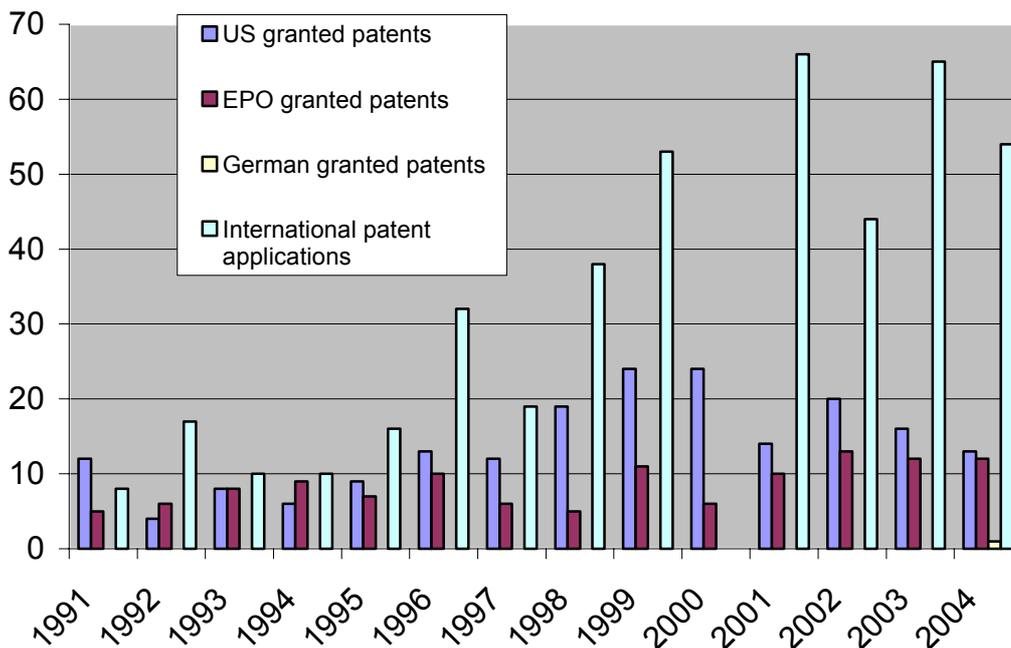
<sup>16</sup> Prof. Robert Cook-Deegan, Director, and Whitney Laemmler conducted the work on these patent searches. WIPO wishes to thank them and the Duke Center for having generously conducted the searches and shared their experience in developing the algorithms.

<sup>17</sup> Available online at <<http://www.law.duke.edu/gelp/>>



### 7.2.1 Banana/plantain (*Musa*)

41. For *Musa* the patent searches resulted in the following data set, organized by year, jurisdiction and type of patent documents (granted national patents and international applications under the PCT):



### *Relevance for availability and use in the CGRFA context.*

To give some indication of the range of technologies involved, and their relation to banana as a genetic resource, the patents issued in 2004 that were located related to:

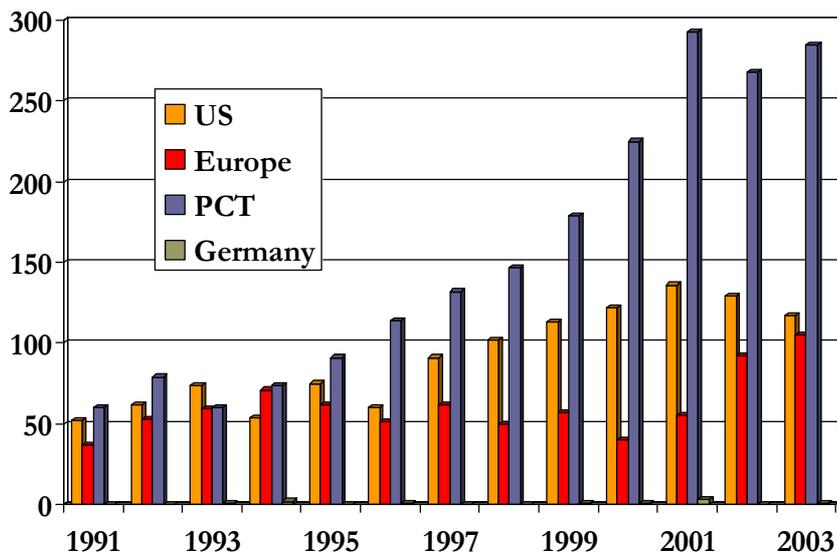
- Use of natural vegetable components as flavoring agents in chewing gum coatings (in which banana was one possibility among many as a 'natural vegetable flavouring agent')

- A method for detecting genomic destabilization in a phenotypically normal plant regenerated from tissue-cultured plant cells, in which banana was one
- Cryopreservation of plant cells, applicable to banana within a range of many other plants
- A food additive comprising fibre preparations from two or more types of fruit or vegetables, which may include banana
- A nutraceutical mangosteen composition, which includes vegetable or fruit juice, which may include banana juice
- A certain isolated nucleic acid molecule, and a transformed plant containing a recombinant construct comprising that nucleic acid, which may be a banana plant among many others.
- A certain isolated nucleic acid molecule, a chimeric gene comprising a promoter active in plants operatively linked to that molecule, and a transgenic plant comprising the chimeric gene, which may be a banana plant among others.
- A method for increasing protein translation in a plant, including a banana plant
- A reduced fat edible spread/syrup composition which may include banana flavouring
- A skin care product which may include banana essence as perfume
- A method for treating or inhibiting a disease of a plant, which may include a banana plant among a wide variety of plants
- A sugarcane ubi9 gene promoter sequence and methods of use thereof, including a method for expressing a nucleic acid sequence of interest in a plant cell, including banana cells among many others.
- A food additive composition which may include dried banana, among many other ingredients.

It may be seen that very few of these patents relate specifically to bananas at all, and that the most relevant to the use of banana as a genetic resource for food and agriculture appears to be in relation to disease control and various methods of transgenic modification of banana plants among a range of other plants.

### 7.2.2. *Beans (Phaseolus)*

42. For *Phaseolus*, the patent searches resulted in the following data set, organized by year, jurisdiction and type of patent documents (granted national patents and international applications under the PCT):



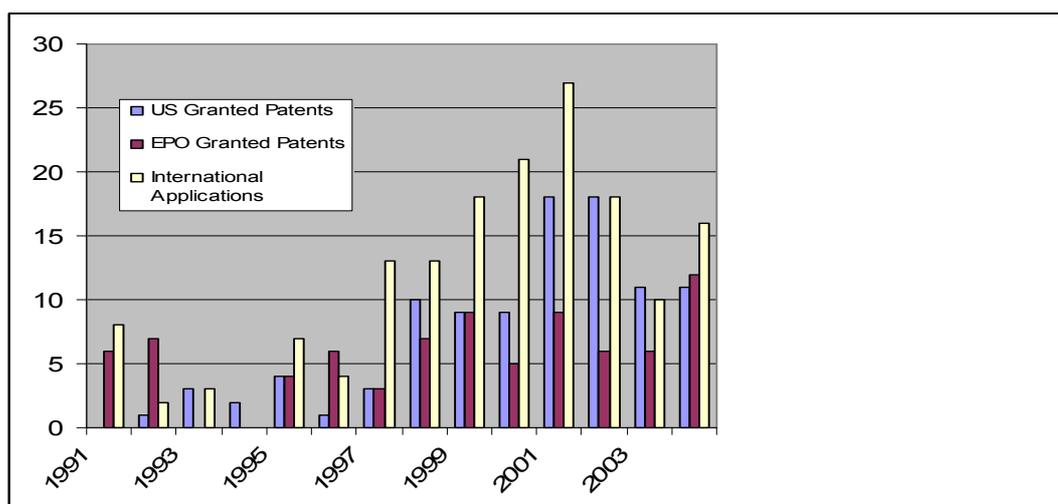
### ***Relevance for availability and use in the CGRFA context.***

To place these figures in context in terms of their relevance to availability and use of PGRFA, following is the brief content of a random sampling of the recent international PCT filings caught by this search:

- An ambient stable and starch-comprising food product.
- Polypeptides having an amylase activity, polynucleotides encoding the polypeptides, and methods for making and using these polynucleotides and polypeptides.
- Transformed plant cells and plants comprising an inactivated or down-regulated gene resulting in increased tolerance and/or resistance to environmental stress, and methods of producing such plant cells or plants.
- DNA constructs and methods to enhance the production of commercially viable transgenic plants
- Methods and compositions, e.g., to reduce interference from non-specific binding sample constituents in a migration shift assay.
- A process for the preparation of a vanilla extract, consisting in subjecting vanilla green beans to accelerated browning followed by extractive/enzymatic treatment.
- Cationic, oxidized polysaccharides in conditioning applications, with use in household and personal care products
- Use of genes for increasing the oil content in plants
- Nucleic acid sequences encoding proteins associated with abiotic stress response and plant cells and plants with increased tolerance to environmental stress

### ***7.2.3 Cassava***

43. For cassava the patent searches resulted in the following data set, organized by year, jurisdiction and type of patent documents (granted national patents and international applications under the PCT):



### ***Relevance for availability and use in the CGRFA context.***

A brief survey of the inventions claimed in the most recent US patents disclosed by this search may illustrate the potential impact on accessibility and use. These inventions relate to:

- A protein supplemented cooked dough product, which uses a starch-containing material which may be derived from cassava.
- Various plant transformation technologies using cassava mosaic viruses as vectors, or conferring resistance to such viruses
- Specific isolated nucleic acids which may be used to develop transgenic plants, including cassava plants among many others.
- A method of genotyping, potentially applied to cassava as for other crops.
- A method of preparing dehydrated potato products, potentially using cassava starch among starch of many other origins.
- A nucleic acid encoding a protein involved in photoperiodism and circadian rhythms, which may be introduced into a range of plants including cassava.

Accordingly, it can be assumed that a relatively small number of these patents would have direct bearing on access and use of PGRFA in the international system, apart from uses that involve the application of novel methods to create new transgenic plants from cassava that is obtained from the system – so that it may impact upon ‘use’ of the resources in that sense, rather than specifically directed at cassava PGR *per se*. Whatever the number of patents in force that direct, it may be contrasted with the total holding of CIAT & ICRISAT accessions of 7972 reported in CGRFA document 10/04/6.

### ***7.3 Observations and information that could result from the sample searches***

44. This document intentionally does not seek to draw conclusions from the preliminary data sets resulting from the sample searches on the effects that patent activity might have on the availability of genetic material of those crops, because the methods, coverage and analysis still need to be improved before solid conclusions can be drawn. Most importantly, claims of identified patents would have to be read and interpreted. This is made clear from the brief surveys of the random selection of patents noted above. The immediate statistics disclosed reveal little more than a general increase of interest in plant resources in broad industrial and technological applications, much of which appears to have only tangential relevance to the area of interest to the Commission and the international system. A significant number of patents affect ‘use’ of the specified crops only in the potential application of patented methods to produce new transgenic plants (typically, a wide range of plants, not focused on the nominated crop as such), rather than restricting use of plant genetic resources *per se*.

### 7.3.1 Key observations

45. The following initial general observations are offered for consideration:
- Firstly, it is difficult for a search of this nature to focus with any precision on patents that are relevant to accessibility and use of specific crops under the international system. The compilation of raw statistics may be misleading or at least may provide little substantively useful information. At most, the patent searches conducted give the most general form of indication of trends in the broad industrial and technological use of the relevant crops and their derivatives in a wide range of applications.
  - Secondly, it is more likely to be beneficial in assessing impact on accessibility and use to develop an overall patent landscape concerning crops of interest. This entails an holistic or composite approach to assembling and interpreting data, taking account of such issues as the actual scope of claims, the legal status of patents, the geographical distribution of any relevant patents, and patterns of ownership of relevant patents. It should be noted that patents apply within precise geographical limits, specifically within the jurisdictions for which they are granted, and no single patent can therefore have overall impact on accessibility and use within a truly international system, such as is conceived under the network and the treaty.
  - A further need is to broaden the geographical scope, the scope of crops covered, and the qualitative analysis of the patent data, if it is to provide any useful guidance at all. This preliminary report essentially only serves to flag the practical issues and the need for further guidance on how this study should proceed.
  - A key source of imprecision is the fact that of the patents disclosed, they rarely relate to a PGR as such (for example, as defined by an accession number in a culture collection). Many patents disclosed are not solely focused on the nominated crop at all, but rather relate to various uses of a much wider range of plants, including the nominated crop among several or many others.
  - Above all, the study illustrates how differing conceptions of ‘accessibility and use’ of genetic resources can lead to very different conclusions based on the patents disclosed. Any further work should aim at clarifying these different options and their implications – in short, at clarifying the forms of accessibility and use that are relevant - on the basis of any guidance from this Commission and its members, either formally or informally. If, for example, the kind of ‘use’ that is intended concerns the use of novel methods for genetic transformation, certain patents may be relevant to this use (at least in the jurisdictions where they have legal effect), but would be irrelevant to other forms of use of the relevant PGR.
46. A key constraint on this information is that set by the territorial nature of patents, and the restriction of their legal effect solely to the jurisdiction for which they are granted. This contrasts with the international character of the *ex situ* network and treaty system. Any direct effect of patents disclosed in the searches on accessibility and use would be limited to the jurisdictions in which they have legal effect. This suggests that a wider geographical
47. However, the sample searches have yielded general insights into the general level of patent activity in relation to the technological and industrial environment relevant to the crops selected since the 1980s.

*Chronological differences: change of numbers of patents/patent applications over time.* The data seem to indicate that the number of patent applications and granted patents have risen especially since the mid 1990s, broadly levelling off since around 1999-2000. The peak in activity has occurred at different times.

*Geographical aspects: in which jurisdictions patent applications were filed and patents granted.* The data sets seem to clearly indicate that the highest level of national patent activity has occurred in the United States for the three crops examined here. International

applications under the PCT system are higher than the level of granted national or regional patents.

*Crop-specific aspects: different levels of patent activity for different crops.* In respect of the three crops that were selected for the sample searches, the resulting data sets show quite distinct levels of patent activity. The highest numbers of filed patent applications and granted patents is found in relation to banana/plantain, followed by beans, millet and cassava. Some other crops covered by the international system are known to have significantly higher levels of activity than those disclosed for the current list of crops used. This observation must be tempered, however, by the observation that many of the patents disclosed are not crop-specific in themselves.

48. This selection already introduced a key limitation on the interpretation of the searches: it meant that some of the more economically important crops in the developed world were not included, even though the searching was focused on jurisdictions in the major developed world economies (due solely to the relatively greater ease of access to such data for such an initial, exploratory search). This may introduce a skew into the data disclosed, with relatively few patents disclosed relating specifically to new crops as such (as discussed below). Accordingly, this choice of crops in itself may need to be revisited for further work, while acknowledging that this is likely to lead to a much greater amount of raw data to be examined and clarified.

## **VIII. LIMITATIONS OF SAMPLE SEARCHES AND THEIR DEVELOPMENT**

49. Several key limitations circumscribed the conduct of the sample searches for this document and will affect the further development of the methodology for the study requested by the CGRFA.

50. The main limitation is that imposed by cost and resources, affecting both the capacity and reach of searches, and the capacity fully to interpret the raw data disclosed. Apart from the cost of using 'value-added' proprietary patent databases, further costs are imposed by reading and interpreting claims, which would require the time of experts to read and interpret the patents (especially the claims sections). Creating databases of the selected patents could be done at relatively low cost (probably in the range of \$5,000) by using software developed by Richard Burgess and made available at very low cost to the DNA Patent Database. The DNA Patent Database has a license to search software that might conceivably be extended to such patent collections, depending on details of who posts them and how they are posted. Or existing patent databases with search capacity, such as the BIOS resource at CAMBIA, may present opportunities.

51. The second limitation is the absence of developing country patents. Few developing country patents are catalogued by Delphion or other major patent international databases. For example, Delphion has good coverage of Australian, Canadian, European, Japanese, and US patents and patent applications, but does not provide complete and claims-searchable data for developing country jurisdictions other than those covered by INPADOC. INPADOC lists front matter, only, and claims searching is not currently possible. In this regard, WIPO may be able to work with the national patent offices of its developing country Member States if required by the CGRFA to fill the gaps with first-hand patent data. While many PCT applications designate many developing countries, this does not imply that national patent applications will actually be pursued in those countries.

52. A further constraint concerns the capacity of search tools (including both the search engines of databases as well as classification systems like the IPC) to support searches that reflect the highly nuanced distinctions which the multilateral system under the International Treaty makes in access to and use of PGRFA, such as, for example, the distinction of access to PGRFA for food and feed purposes on the one hand and for non-food and non-feed purposes

on the other. This has already been demonstrated in the review of sample patents discussed above. Such distinctions could be addressed, if necessary, through identifying patents by simple searches, followed by analysis of patent claims by trained readers. Less detailed “indicator” data could be based on simple searches, if required, following some refinement of the search algorithm and manual spot checks.

53. Should more precise information about patents become available, this would in turn create a need for greater specificity about the scope of coverage of the PGRFA held in the relevant international systems. This underscores the continuing utility of a two-way flow of information about genetic resources between the patent system and the international system concerning PGRFA.

54. The immediate practical limitations on continuing this work are the limited funding available to FAO and WIPO for the conduct of the requested study, and the time and expertise needed to read and interpret identified patents, as well as the need for further clarity of the nature of ‘accessibility and use’ that will be of interest to the Commission. If such constraints could be addressed, numerous avenues of potential and promising work might arise based on the ground work done to date by FAO and WIPO.

55. A further question concerns other forms of intellectual property, apart from the general utility patents considered in this search. These include, in the US context, the plant patent system, and more generally the systems of plant breeders rights, in particular those developed within the international framework established by UPOV.

## IX. POSSIBLE OPTIONS FOR FUTURE WORK

56. As indicated above, the methodology developed so far allows for the identification of crude levels of patenting activity for the different crops covered by the International Network and the International Treaty. This could be seen as a first rough cut of data to be progressively refined and focused, over time leading to a more intelligible and useful landscape of relevant inventions. To achieve this, however, is a major task. To address the more specific aspects of how patents may affect the availability of these crops and related issues, there would be a range of possible follow-up activities resulting from this initial work. These options for possible future work are listed here in five general headings.

(i) *Improving, focussing and completing the patent searches by further developing the methodology, search coverage and statistical analysis of patenting trends over PGRFA*

57. This would entail the follow-up work already specified above, and would lead to an advanced understanding of international patenting trends on individual crops from the International Network and the International Treaty by specific countries, regions or sectors. It would involve further specificity and sensitivity testing as already outlined above; ensuring broader coverage of the searches; and conducting actual analysis of possible effects on availability of PGRFA from the Network and the Treaty in relation to specific patents with relevant claim scope. It would also involve improving and focusing the analytical categories in terms of IPC classes or types of patent claims, so as to filter out many more of the irrelevant patents. The findings could also be related to longer-term patenting trends, or broader legal issues such as different patent regimes and their relationship with plant variety protection.

(ii) *Deepening the study of IP issues by focusing on specific technologies and related freedom-to-operate questions*

58. A patent must be considered in its legal context, especially where the concern relates to its impact on others’ freedom to operate: this has several aspects, ranging across claim interpretation, the nature of rights granted, and the legal status and jurisdictional reach of any specific patent. This highlights the need to consider in more depth the legal issues that affect

the availability and use of any specific technology or crop. Such studies would provide detailed information about the patent landscape surrounding selected inventions that constitute PGRFA covered by the International Network and the International Treaty. Certain specific technology areas would need to be selected for pilot studies in this area. Such follow-up studies could focus on particular patent families and technologies, and provide an analysis of freedom to operate.

*(iii) Making available a joint online information resource for the IP needs of the agricultural sector in developing countries*

59. This initial study has, above all, highlighted the value of much wider access to and reference to actual patent documents, as opposed to the kind of broad conclusions that raw statistics would reveal. This points to the benefits that would flow from enhanced access to relevant patent data by a wider range of stakeholders in the International Network and Treaty. Based on the data sets of PGRFA-related patent information obtained from the aforementioned sample searches, a range of tailor-made IP information resources, would be customized to the needs of the agricultural sector in developing countries and be made available on the Internet. Such information resources could be tailor-made for the needs of small and medium size enterprises in the agricultural sector of developing countries and could build upon existing information resources and related IP management initiatives.

*(iv) Correlating patent data with other data sets*

60. Further consideration could be given to how patent data may be correlated with other data sets relevant to holdings and use of plant genetic resources. The potential use of the SINGER database developed by IPGRI in relation to patent search and examination suggests that there may be further prospects for building systematic linkages between datasets to provide a richer base of information about relevant PGRFA, and the circumstances and of their holdings and use, for the benefit of policymakers such as the Commission.

## **X. CONCLUSIONS**

The FAO and WIPO have worked together closely for the past seven years and, at the request of the CGRFA at its ninth session, the Secretariats have cooperated towards “preparing a study on how intellectual property rights may affect the availability and use of material from the International Network and the International Treaty.” This preliminary study has highlighted some possible directions, while stressing the need for careful review of available patent data and the need for the data to be assessed in its full operational context before any judgment can be made about its relationship with use and accessibility of covered material. A progressive, interactive approach, based on the options identified for further work, may be the most productive, so that the study can be developed over time with the benefit of enhanced data sets, improved capacity to search for and analyse data, and further guidance and practical insight from a wider range of stakeholders, including those directly involved with practical questions of use and accessibility.