

# **BENEFIT-SHARING CASE STUDY**

## **The Genetic Resources Recognition Fund of the University of California, Davis**

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are entirely the responsibility of the authors.

**Submission to the Executive Secretary of the Convention on Biological Diversity  
by the Royal Botanic Gardens, Kew**

## OVERVIEW

### MAIN ACTORS

- University of California at Davis (UC Davis): Professor Pamela Ronald, Assistant Professor of Plant Pathology.
- International Rice Research Institute (IRRI): Dr. Gurdev Khush.
- Stanford University: Professor John Barton.
- Two, un-named agricultural biotechnology companies that have licensed the gene *Xa21* from UC Davis.<sup>1</sup>

### OTHER ACTORS

- Central Rice Research Institute (CRRRI), Cuttack, India: Dr. Devadath obtained a strain of *Oryza barthii*<sup>2</sup> from Mali and provided it to Dr. Chaudhury of Rajendra Agricultural University.
- Rajendra Agricultural University (RAU), India: Dr. R.C. Chaudhury provided the resistant strain of *O.barthii* to Dr. Khush of IRRI.
- Cornell University: John C. Sanford developed a ‘gun’ to shoot microscopic particles coated with DNA into the cells of the recipient plant. Steven D. Tanksley and Susan R. McCouch produced a genetic map for rice, identifying useful markers on the 12 rice chromosomes.
- Japanese Rice Genome Project: Dr. Sasaki and Dr. Saito produced genetic maps for rice.
- International Laboratory for Tropical Agricultural Biotechnology (ILTAB): Dr. Claude Fauquet and his staff transformed *Xa21* into rice variety Taipei 309.
- Chinese Academy of Agricultural Sciences in Hainan Province, China: collaborating in rice transformations, evaluation and field trials.
- Rockefeller Foundation: providing financial support for field trials on transgenic rice in China, and training of Chinese scientists.
- University of Mali: Dr. Aboubacar Toure, head of Mali’s Sorghum Breeding Programme and Director General of the University, suggested that he could propose candidates for Fellowships for sponsorship by the Genetic Resources Recognition Fund.

### ECOSYSTEMS, SPECIES AND GENETIC RESOURCES

*Oryza longistaminata*, a wild species of rice native to sub-Saharan Africa, found to be resistant against the bacterium *Xanthomonas oryzae* pv. *oryzae* (‘Xoo’). A gene, ‘*Xa21*’, from a specimen of *O. longistaminata* collected in Mali was introduced into the DNA of a number of other rice varieties and tested against 31 different Xoo strains from eight countries.

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<sup>1</sup> The authors contacted the companies through Professor Ronald when preparing this case study, but the companies did not wish to be identified nor to communicate about the case study.

<sup>2</sup> The sample in question was originally classified as *O.barthii*, but subsequently reclassified as *O. longistaminata*. Personal communication with Dr. Gurdev Khush, 18 February 1998 and Dr. Michael Jackson, 6 April 1998.

## **TYPE OF BENEFIT-SHARING ARRANGEMENT AND EXPECTED RESULTS**

UC Davis has established a Genetic Resources Recognition Fund (GRRF). One year after each licensee company commercialises a product based on a gene isolated by UC Davis, it will make a lump-sum payment into the Fund. The Fund will be used to finance Fellowships at UC Davis for students from source countries<sup>3</sup>. In addition, researchers, including institutions in source countries, will be able to access, at cost price, genes and transgenic varieties produced by UC Davis, subject to a material transfer agreement prohibiting commercialisation without the express, written consent of UC Davis.

## **TIME FRAME ADDRESSED**

A specimen of the wild rice species *Oryza longistaminata* from Mali was evaluated by Indian researchers for its resistance to rice blight in 1977. Between 1978 and 1990, IRRI bred the resistance to rice blight from *Oryza longistaminata* into rice variety IR24 and discovered that blight resistance was attributable to a section of DNA, found on a single chromosome, that they termed *Xa21*. In 1990, Professor Pamela Ronald and her colleagues at Cornell University started work to identify the location of *Xa21* on the rice genome, which she continued when she moved to UC Davis in 1992. In 1995, the UC Davis team identified and cloned *Xa21*. UC Davis filed a patent on the *Xa21* gene sequence in 1995, and in June 1996, with assistance from Professor John Barton of Stanford University, UC Davis established the Genetic Resources Recognition Fund. In July 1996 and January 1997, UC Davis entered into agreements licensing the gene to two agricultural biotechnology companies, and will use the Genetic Resources Recognition Fund as a mechanism to share any resulting financial benefits by funding Fellowships for scholars from source countries such as Mali.

## **RELEVANCE TO THE CONVENTION**

- Access to genetic resources and benefit-sharing
- Facilitated access to strains of major crops for research
- Access to genetic resources from *ex situ* collections made prior to the entry into force of the Convention (i.e. those excluded from the access and benefit-sharing provisions of the Convention by virtue of Article 15(3))
- Terms of access and benefit-sharing for development of new varieties of crop based on introduction of unadapted, exotic germplasm
- Benefit-sharing in agriculture
- Role of university in voluntary initiative to share benefits
- Trust fund as mechanism for benefit-sharing

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<sup>3</sup> The CBD itself does not use the term 'source countries'. Instead, Article 15 refers to 'the genetic resources being provided by a Contracting Party' (i.e. those to which the access and benefit-sharing obligations of the Convention attach) as 'those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention'. Article 2 defines 'country of origin' as 'the country which possesses those genetic resources in in-situ conditions', and 'in situ conditions' as 'conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties'. The term 'source countries' is used in this case study, as Prof. Ronald has yet to determine from exactly which countries scholars to be sponsored by the Genetic Resources Recognition Fund will come. Depending on the magnitude of the monetary benefits that arise from the commercialisation of *Xa21*, scholarships may be offered to students from Mali (a country of origin that originally provided the genetic resources in question), other countries where *O. longistaminata* is found in its natural habitat (other countries of origin, but which did not provide the original sample), and, more broadly still, other countries that are countries of origin of other genes that may, in the future, be licensed to companies by UC Davis, or even of all the genes on which UC Davis conducts research (whether or not these other genes are licensed or commercialised). The entire pool of countries whose students may thus be eligible for scholarships at UC Davis are referred to in this case study as 'source countries'.

- Biotechnology/genetic engineering; biosafety
- Relevant to Articles: 1, 10, 15(1), 15(2), 15(3), 15(4), 15(5), 15(6), 15(7), 16, 19(1), 19(2).

## CONTEXT

### **BIOLOGICAL RESOURCES AND PHYSICAL ENVIRONMENT**

*Oryza longistaminata* is a rhizomatous, perennial species of rice found on the African mainland and in Madagascar. The sample from which the gene that is the subject of this case was taken was originally collected in Mali. The species grows under several conditions. It can be found in completely wild habitats, such as on the edge of permanent water pools, where its rhizomes enable it to survive periods of dessication. *O. longistaminata* can also be found on the margins of cultivated land, such as in ditches, and even in cultivated areas such as rice fields themselves.

*O. longistaminata* itself has a low yield and poor taste, and thus this wild rice species is of comparatively little interest as a crop in its own right. However, it is found to be resistant against another species central to this case study: the bacterium *Xanthomonas oryzae* pv. *oryzae* ('Xoo'). This case study also involves other varieties of rice, as the gene 'Xa21' from *O. longistaminata* has been introduced into the DNA of several rice varieties such as Taipei 309 (an old variety that is no longer grown, but is easily transformed and susceptible to Xoo), IR24, IR64, IR72 and Ming Hui 63, a variety that is widely grown in China. The transgenic variety Taipei 309 has been tested against 31 different Xoo strains from eight countries.

### **REGIONAL, NATIONAL, LOCAL LEGAL/POLICY FRAMEWORK**

The sample of wild rice from which *Xa21* was isolated originated in Mali and was characterised at the International Rice Research Institute (IRRI), based in the Philippines. The genetic resources concerned are 'plant genetic resources for food and agriculture', as the term is used by the United Nations Food and Agriculture Organisation (FAO), and were held in ex situ collections by the time that the CBD entered into force. The gene *Xa21* was patented by UC Davis and licensed to companies for commercialisation. Thus the policy framework for this case study comprises five components: the law and policy on access and benefit-sharing in Mali;<sup>4</sup> international law and policy on access to plant genetic resources for food and agriculture; the policies on access and benefit-sharing and intellectual property rights operated by IRRI; the law on access to genetic resources in the Philippines, and the policy under development at the University of California, Davis.

#### **International law and policy on access to plant genetic resources for food and agriculture**

In 1983, the members of the FAO Commission on Plant Genetic Resources ('the Commission')<sup>5</sup> adopted the International Undertaking on Plant Genetic Resources ('the

<sup>4</sup> Regrettably, prior to COP4, the authors have not been able to make contact with policy-makers concerned with access and benefit-sharing in Mali. We hope to fill this important gap during the COP and to submit an amended version of this paper in the following weeks.

<sup>5</sup> The FAO established the intergovernmental Commission on Plant Genetic Resources (CPGR) in 1983. Renamed the Commission on Genetic Resources for Food and Agriculture (CGRFA) in 1995, the Commission is currently comprised of the 151 member States of the FAO. The CGRFA coordinates, oversees and monitors the development of the Global System for the Conservation and Utilization of Plant Genetic Resources for Food and

Undertaking'). The objective of this non-binding instrument is to 'ensure that plant genetic resources of economic and/or social interests, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes'.<sup>6</sup> Article 5 of the Undertaking refers to the 'principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction'. Disquiet on the part of plant breeders that this principle would require them to make their breeding materials available led to the adoption of Resolution 3 of the FAO Conference of 1991, which recognises that the concept of mankind's heritage, enshrined in the Undertaking, 'is subject to the sovereignty of the states over their plant genetic resources'.<sup>7</sup>

The agreed text of the Convention on Biological Diversity adopted on 22 May 1992 endorsed States' sovereign rights over their natural biological resources and the consequent authority of national governments to determine access to genetic resources. According to the Convention, such access shall be subject to Parties' prior informed consent,<sup>8</sup> and on mutually agreed terms<sup>9</sup> that promote the fair and equitable sharing of benefits<sup>10</sup>. Article 15(3) of the Convention concerns access to "only those [genetic resources] that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention". The access and benefit-sharing provisions of the Convention thus do not apply to *ex situ* collections acquired prior to the entry into force of the Convention. Approximately 6.1 million plant samples are currently maintained in *ex situ* collections worldwide,<sup>11</sup> many of which are housed in collections that are regularly accessed by researchers and breeders, giving rise to a host of monetary and non-monetary benefits. Consequently, Resolution 3 of the 'Nairobi Final Act', in which the text of the CBD was adopted, recognised the need to seek solutions to outstanding matters, in particular, 'access to *ex situ* collections not acquired in accordance with this Convention', including *ex situ* collections acquired prior to the entry into force of the Convention, such as those of *O.longistaminata* and IRBB21 referred to in this case study; and 'the question of farmers' rights'.<sup>12</sup>

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Agriculture, which is comprised of the Commission itself and the non-binding International Undertaking on Plant Genetic Resources, the rolling Global Plan of Action and International Fund for Plant Genetic Resources (PGR), the World Information and Early Warning System (WIEWS), Codes of Conduct and Guidelines for the Collection and Transfer of Germplasm, and the International Network of Ex Situ Collections under the auspices of the FAO, an international network of in situ conservation areas and crop-related networks . See Earth Negotiations Bulletin, Vol.9 No.68, 26 May 1997 for this and other useful summaries concerning the history and institutions of the FAO concerned with PGRFA.

<sup>6</sup> Article 1, International Undertaking on Plant Genetic Resources, Resolution 8/83, Twenty-second Session of the FAO Conference, Rome 5-23 November 1983. CPGR-Ex1/94/Inf.1, FAO, Rome, September 1994. The article goes on to state that 'This Undertaking is based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction'

<sup>7</sup> Resolution 3 of the FAO Conference of 1991 endorses the principle that states have sovereign rights over their plant genetic resources, and that breeders' lines and farmers' breeding material should be made available only at the discretion of their developers during the period of development.

<sup>8</sup> 'Unless otherwise determined'. See CBD Article 15(5).

<sup>9</sup> See CBD Article 15(4).

<sup>10</sup> More precisely, CBD Article 15(7) requires each Contracting Party to 'take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms'.

<sup>11</sup> FAO, 1996. Report on the State of the World's Plant Genetic Resources, Document CGRFA-EX2/96/2 of the Second Extraordinary Session of the FAO Commission on Genetic Resources for Food and Agriculture, 22-27 April, 1996.

<sup>12</sup> UNEP, 1992. Resolution 3 of the Nairobi Final Act of the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity, UNEP, Nairobi.

The FAO Commission agreed, through resolution 7/93, that the Undertaking should be revised to be in harmony with the Convention, and requested the Director-General of the FAO to provide a forum for negotiations among governments concerning ‘the adaptation of the International Undertaking on Plant Genetic Resources, in harmony with the CBD’; ‘consideration of the issue of access on mutually agreed terms to plant genetic resources, including *ex situ* collections not addressed by the Convention’; and ‘the issue of realization of Farmers’ Rights’. The Commission has met some five times to discuss the revision of the Undertaking,<sup>13</sup> and will next meet in June 1997.

In the future, the mechanisms for sharing the benefits that arise from the use of plant genetic resources for food and agriculture (PGRFA), including those held in *ex situ* collections, and what is regarded as best practice in access and benefit-sharing for PGRFA will be heavily influenced by the outcome of the revision of the Undertaking. The revised Undertaking is likely to provide a framework for approaches to benefit-sharing by the countries adhering to the new Undertaking, by the International Agricultural Research Centres of the Consultative Group on International Agricultural Research, and by institutions such as universities, which may be able to participate in any multilateral system for access and benefit-sharing that emerges from the revision of the Undertaking.

### **The policy on access and benefit-sharing and IPRs of the Consultative Group on International Agricultural Research (CGIAR) and its Centres, including IRRI**

Towards the end of the 1980s, the Consultative Group on International Agricultural Research<sup>14</sup> (CGIAR) decided that it needed to respond to the highly politicised and increasingly rancorous international debate about intellectual property rights (IPRs) on plant genetic resources.<sup>15</sup> The first CGIAR policy on plant genetic resources was published in 1989, in which the CGIAR stated its perception of its role as trustee, rather than beneficial owner, of the plant genetic resources held within the International Agricultural Research Centres (IARCs, also known as ‘the Centres’). In 1991, a “CGIAR Working Document on Genetic Resources and Intellectual Property Rights” was adopted, pursuant to which materials from the genebanks at the IARCs continued to be “freely available” in accordance with the 1989 policy.<sup>16</sup>

In 1990, the Centres began to explore the possibility of bringing the collections held in genebanks of the IARCs under the governance of an intergovernmental organisation,<sup>17</sup> and in

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<sup>13</sup> For a more detailed introduction to the background, legal and policy issues and progress with the revision of the Undertaking, see ten Kate, Kerry and Lasen-Diaz, Carolina, 1997: *The Undertaking Revisited: A commentary on the revision of the International Undertaking on Plant Genetic Resources for Food and Agriculture*. Review of European Community and International Environmental Law. Foundation for International Environmental Law and Development, London.

<sup>14</sup> The CGIAR is an informal association of 57 public and private sector organisations, including the International Agricultural Research Centres, concerned with agricultural science.

<sup>15</sup> Hawtin, Geoffrey and Timothy Reeves, 1997. Intellectual Property Rights and Access to Genetic Resources in the Consultative Group on International Agricultural Research (CGIAR). Paper presented at the workshop “Intellectual Property Rights III - Global Genetic Resources: Access and Property Rights.” 4-6 June 1997, Washington DC. In 1987, an Inter-Centre Working Group on Genetic Resources (ICWG-GR), comprising the heads of the genetic resources programmes of the various Centres, was established to develop common policies.

<sup>16</sup> A sub-committee on IPRs of the Centre Directors’ Committee presented a paper setting out principles on IPRs, biosafety and plant genetic resources, but differences of opinion among members of the CGIAR led to the adoption of only a tentative working document. Hawtin and Reeves, 1997.

<sup>17</sup> Hawtin and Reeves (op.cit.) set out some of the reasons for bringing the CGIAR collections within the FAO International Network of Ex Situ Collections:

‘Other concerns were rooted in the fact that the bulk of funding for the CGIAR came from developed countries, and that nationals of these countries held many of the key positions within the system. “Control” of the system, it was argued, was dominated by developed countries -- the same countries where IPRs and the privatization of science were increasingly shaping the research and development

October 1994, agreements were signed between the FAO and each of twelve IARCs, including IRRI, by virtue of which each Centre was to hold designated collections of germplasm “in trust for the international community”.<sup>18</sup> Article 3(b) of each agreement provides that “[t]he Centre shall not claim legal ownership over the designated germplasm, nor shall it seek any intellectual property rights over the germplasm or related information”. Under Article 9, each Centre “undertakes to make samples of the designated germplasm and related information available directly to users or through the FAO, for the purpose of scientific research, plant breeding or genetic resource conservation without restriction”. According to Article 10, “[w]here samples of the designated germplasm and/or related information are transferred to any other person or institution, the Centre 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)”.<sup>19</sup>

When the CGIAR Centres signed the agreements with the FAO in October 1994, each Centre was free to decide which germplasm from its collections was to be covered by the agreement. Each Centre provided a list of this ‘designated’ germplasm. The Centres ‘designated’ different quantities and kinds of germplasm, based, in part, upon the obligations of each Centre to commit to the long-term conservation of all designated germplasm.<sup>20</sup> At the time, the Centro Internacional de Mejoramiento de Maíz y Trigo (CIMMYT) for example, did not designate its breeding lines, although many of them have been designated subsequently.<sup>21</sup> IRRI, by contrast, chose to designate the entire collection that was held in its ‘International Rice Centre’ in October 1994, including those of its own breeding lines that were deposited in the genebank. IRRI’s decision was based on two factors: the sense of obligation to maintain germplasm that had been placed in the collection, along with the need to meet the requirements for long-term conservation imposed by the agreement with FAO; and the unfeasibility of sorting manually through more than 80,000 records, as would have been required to distinguish between ‘designated’ and ‘non-designated’ germplasm.<sup>22</sup>

For the facts of this case study it is important to note that the breeders in the CGIAR Centres do not place all their breeding lines in the Centres’ genebanks, but generally contribute only those lines that they feel to be fully developed and of particular value for safe-keeping. Some experimental breeding lines are thus not designated.<sup>23</sup> It would appear that the breeding line IRBB21, of which Professor Ronald obtained a sample, was not designated in October 1994, and has not been designated subsequently.<sup>24</sup> It is more likely that the original source of *Xa21*, the specimen of *O. longistaminata*, is maintained in IRRI’s International Rice Centre genebank

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environment. Based on this argument and the fact that so much of the germplasm underpinning the CGIAR research originated in developing countries, there were fears that the system would come under enormous pressure to act in the primary interests of the North, even to the extent of restricting access to germplasm by developing countries through the application of IPRs.

‘In the light of these concerns, the Centres began, as early as 1990, to hold discussions with the FAO on the possibility of bringing the CGIAR collections within the FAO International Network of Ex Situ Collections.’

<sup>18</sup> Article 3 of the FAO-CGIAR Agreement, October, 1994, FAO, Rome.

<sup>19</sup> In 1994, the CGIAR also developed, but decided not to adopt formally, “Guiding Principles for the CGIAR Centers on Intellectual Property and Genetic Resources”, according to paragraph 5 of which “[t]he Centers will not claim legal ownership nor apply intellectual property protection to the germplasm they hold in trust, and will require recipients of the germplasm to observe the same conditions, in accordance with the agreements signed with FAO. These ‘Guiding Principles’ were developed in September 1994. See Hawtin, Geoffrey and Timothy Reeves, 1997, *supra*.

<sup>20</sup> Personal communication, Dr. Michael Jackson, IRRI, 18 April 1998.

<sup>21</sup> Personal communication, Dr. Jane Toll, IPGRI, 20 April 1998.

<sup>22</sup> Personal communication, Dr. Michael Jackson, IRRI, 18 April 1998.

<sup>23</sup> Personal communication, Dr. Jane Toll, IPGRI, 20 April 1998.

<sup>24</sup> Personal communication, Dr. Michael Jackson, IRRI, 18 April 1998.

and is thus designated, although it has not yet been possible to ascertain which accession was used to breed IRBB21, nor its accession number.<sup>25</sup>

It is also important to consider the effect of a clause, such as those contained in the FAO-CGIAR Centres agreements and in the MTAs used by the individual Centres, which provides that recipients of germplasm shall not 'seek any intellectual property rights over the germplasm or related information'. Some observers interpret this provision to mean that a recipient of designated germplasm from a CGIAR Centre would be prohibited from taking out plant variety protection on unchanged material, but would be entitled to take out a patent on an 'invention' derived from such material.<sup>26</sup> This interpretation could be based on the fact that patent offices and courts in some jurisdictions, for example in the United States and in Europe, allow patents on genes, typically for the development of a gene sequence or the isolation of a protein. Such innovations are considered patentable as the activities concerned are currently judged to be 'non-obvious', and the results are not considered a 'product of nature' (and hence, unpatentable), since the individual genes or proteins do not exist in their purified form in nature.<sup>27</sup>

Others hold a different view, interpreting 'intellectual property rights over the germplasm or related information' to include patents on the genes, progeny and derivatives of the materials, and pointing out that the language of the clause does not refer to genotypes or plant varieties, but to the germplasm itself.<sup>28</sup> Some conservators and seed breeders within the CGIAR system hope that the effect of the clause will be to enable recipients of CGIAR material to use it, but not to claim a monopoly on its use.<sup>29</sup>

In 1995, the Inter-Centre Working Group on Genetic Resources (ICWG-GR) recommended that all the Centres should require recipients of genetic resources from the collections to complete a "Standard Order Form" in which the recipient would undertake "not to claim ownership over the material received, nor to seek intellectual property rights over that germplasm or related information" and to ensure that any subsequent person or institution to whom the material was sent would be "bound by the same provision". The material would then be sent accompanied by a "Shipment Notice" containing the same terms, which the recipient would sign.

Subsequently, IRRI adopted this procedure, and, since 1996, has supplied designated material under a material transfer agreement containing these terms.<sup>30</sup>

In February 1998, the CGIAR called for a moratorium on the granting of intellectual property rights on designated plant germplasm held in the Centres.<sup>31</sup> CGIAR Chairman Dr. Ismail Serageldin expressed the hope that recipients of designated material would honour the spirit of the 1994 agreements with the FAO. Although recipients of materials from Centres are now

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<sup>25</sup> Ibid.

<sup>26</sup> Personal communication, Prof. John Barton, Stanford University, 3 April 1998

<sup>27</sup> Personal communication, Prof. John Barton, Stanford University, 3 April 1998 and with Dr. Michael Gollin, Spencer & Frank, 20 April 1998.

<sup>28</sup> Personal communication, Mr. Pat Mooney, RAFI, 20 April 1998.

<sup>29</sup> Personal communication with Dr. Michael Jackson, IRRI, 18 April 1998

<sup>30</sup> While all designated germplasm from IRRI's genebank collection covered by IRRI's October 1994 agreement with the FAO is sent out under a material transfer agreement, the same is not true of materials from IRRI's breeding programme. Materials from IRRI's breeding programme are only released subject to a material transfer agreement (MTA) if they are sent to private companies. Improved materials are currently sent to National Agricultural Research Systems (NARS) without the use of an MTA. Personal communication, Dr. Michael Jackson, IRRI, May 1996, and 6 and 18 April 1998.

<sup>31</sup> CGIAR Press Release, 11 February 1998. <http://www.worldbank.org/html/cgiar/press/germrel.html>.

bound by the terms of material transfer agreements that cover designated germplasm and some other materials, these agreements were introduced after 1994, in response to the agreements between FAO and the Centres. However, the CGIAR hopes that, nonetheless, recipients will not take out IPRs on materials received from Centres before 1994, for which material transfer agreements were not signed.<sup>32</sup>

The call for a moratorium is partly in response to information provided to the CGIAR by the non-governmental organisation Rural Advancement Foundation International (RAFI), revealing that Agriculture Western Australia and the Grains Research and Development Corporation, both Australian government agencies, applied for plant variety rights on two chickpea varieties that were covered under the FAO-CGIAR agreements and obtained from the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) under the material transfer agreement used by the Centres. The agencies withdrew these plant variety right applications on 13 January 1998, following a strong request by ICRISAT that they should do so.<sup>33</sup>

The policies and practices on access and benefit-sharing adopted by the Centres of the CGIAR in the future are likely to be heavily influenced by results of the revision of the Undertaking, as described above.

### **Law on access to genetic resources in the Philippines**

IRRI is based in the Philippines, which, in May 1995, adopted Executive Order No. 247, “Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-Products and Derivatives, for Scientific and Commercial Purposes, and For Other Purposes”, and subsequently, in July 1996, adopted Department Administrative Order No. 96-20, “Subject: Implementing Rules And Regulations on the Prospecting of Biological and Genetic Resources”. These measures provide a framework for access to genetic resources in the Philippines, with obligations for acquiring the prior informed consent of both the government and “indigenous and cultural communities” (Section 2), minimum terms for both commercial and academic research agreements (Section 5), requirements for benefit-sharing, and the establishment of an institutional structure to act as the Competent National Authority on these matters (Sections 6 and 7). The procedural and substantive provisions of these measures are well documented elsewhere.<sup>34</sup>

The effect of the Philippines Executive Order 247 and its Implementing Regulations on access to collections held by IRRI, including designated germplasm, is unclear. Under one interpretation, applicants wishing to access specimens held at IRRI would need to obtain the consent of the Philippine government. However, it is unlikely, but not certain, that any such obligation exists, and, if so, whether it would extend only to specimens originating in the Philippines, or to all the specimens held at IRRI.<sup>35</sup> In practice, IRRI continues to provide access to the materials in its collection under the material transfer agreement described above, but with no recourse to the Philippines authorities for permission to do so.<sup>36</sup>

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<sup>32</sup> Ibid.

<sup>33</sup> Edwards, Rob and Ian Anderson, 1998. Seeds of wrath. New Scientist, London, 14 February. <http://www.newscientist.com/ns/980214/nfocus.html> and personal communication, Dr. Cary Fowler, 13 April 1998.

<sup>34</sup> See, for example, La Vina, A.G.M., Mary Jean Caleda and Lourdes L. Baylon (ed.s), 1996. Regulating Access to Biological and Genetic Resources in the Philippines: A Manual on the Implementation of Executive Order No. 247. Foundation for the Philippines Environment and World Resources Institute.

<sup>35</sup> Personal communication, Mary Jean Caleda, Department of Environment and Natural Resources, Manila. 24 February 1998.

<sup>36</sup> Section 1e of Article II (Objectives and Incidental Powers) of the Charter which accompanies IRRI's agreement with the Philippines of 19 May 1995 describes one of IRRI's functions as “to maintain a rice

## **The policy on access to genetic resources and benefit-sharing of UC Davis**

The policy on access to genetic resources of the University of California, Davis is examined in the following sections.

### **OBJECTIVES**

The mission statement of Professor Ronald's laboratory sets out UC Davis' objective for its work with *Xa21*:

“We are dedicated to international collaborative basic research to investigate the fundamental bases of plant-microbe interactions. We support applications of our research that will lead to increased food production, renew the genetic diversity of the world's crops and reduce inputs of pesticides and herbicides. These goals are consistent with our view that sustainable food production is necessary for reduced population growth and a healthy environment.”<sup>37</sup>

In the long term, Professor Ronald hopes that the transformation of the *Xa21* gene into rice varieties will improve food security through increasing the yield of rice by decreasing rice blight.<sup>38</sup> Furthermore, these varieties could contribute to sustainable agriculture, as the blight resistance gene reduces the need for environmentally damaging pesticides and herbicides.

### **PROCESS FOR ESTABLISHING THE ARRANGEMENTS**

The process by which Professor Ronald established the benefit-sharing arrangements described in this case study consisted of two elements; first, her work with the University of California, Davis to establish a Genetic Resources Recognition Fund; and second, her negotiations with companies interested in access to *Xa21*, which led to their commitments to contribute to the Fund.

After deciding that she would like to devise a mechanism to share with source countries<sup>39</sup> the benefits arising from her work on genetic resources from those countries, Professor Ronald discussed the idea of a Genetic Resources Recognition Fund with John Barton, a Professor of Law at Stanford University who has worked on issues related to access to genetic resources

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genetic[s] resources centre which will collect, store and make available to scientists and institutions all over the world rice germplasm and related genetic materials”. Article XV (Dissolution of the Institute) covers what would happen if IRRI were to be terminated. In these circumstances, “physical plant, equipment and other assets” would become the property of the University of the Philippines System (UPS), but “the Institute's genebank and genetic resources, that shall have been assigned in trust to the Institute for others or donated to the Institute, and shall have been made subject to some other conditions in respect of their disposition upon the dissolution of the Institute” would not become the property of UPS. As this agreement follows the Philippines Executive Order, which was enacted on 18 May 1995, this would suggest that the Philippines government would not be involved in the determination of access to designated germplasm held at IRRI. Personal communication with Dr. Michael Jackson, IRRI, 6 April 1998.

<sup>37</sup> See <http://indica.ucdavis.edu/default.htm>

<sup>38</sup> Personal communications, Prof. Ronald, 18 February, 5 & 6 March 1998.

<sup>39</sup> See footnote 3, supra.

and benefit-sharing for many years.<sup>40</sup> Professor Ronald admits that, as a geneticist, issues of access and benefit-sharing and intellectual property rights lie outside her own expertise. The experience of setting up the Fund with Professor Barton's help involved a steep learning curve for her, for the administration of UC Davis and for the University's technology transfer department, which is responsible for its licensing agreements. The University supported Professor Ronald's initiative, but has not traditionally engaged in benefit-sharing arrangements.

Professor Ronald conducted the negotiations with the companies interested in access to *Xa21*, with help from John Barton and UC Davis' Office for Technology Transfer. Given the novelty of benefit-sharing arrangements in partnerships to develop new crops, few if any of the major actors involved in this case study had much experience of such negotiations and there was little prior experience to learn from. The negotiation process lasted from the autumn of 1994, when discussions between UC Davis and the companies started, to January 1997, when an agreement was signed with the second company.

One key factor that shaped the benefit-sharing arrangement was the need for the timing and mechanism of payment by the companies to match their internal accounting processes. Another important factor was the need to design a benefit-sharing mechanism that fitted within current UC Davis practices. While the rules and procedures for administration of the Genetic Resources Recognition Fund and selection of Fellows have yet to be established,<sup>41</sup> it is possible that they could be based on earlier experience at UC Davis in administering scholarship bursaries.<sup>42</sup>

During the negotiations with the companies, UC Davis proposed that the financial benefits contributed by companies should take the form of a royalty of a certain percentage of sales of the products marketed by the companies based on *Xa21*. However, from the companies' perspective, *Xa21* would only make a small contribution to the genome and desirable traits of any new crop variety developed, so they were not comfortable with an open-ended royalty commitment. Instead, the university and the companies settled on financial benefits consisting of payment of a single lump sum by each company: US\$52,000 in the case of the first company, and US\$30,000 in the case of the second company. Given that only a minute proportion of research actually leads to a successful commercial product, the companies and the inventors settled on "commercialisation" of a successful product, defined as the availability of the product for sale on the market, as the most appropriate trigger for payment of these sums. The benefit-sharing arrangement involves a single payment by each company into the Fund of the agreed sum one year after the commencement of sales by that company of the first new product that makes use of the *Xa21* gene.

When the University was assessing the amount of financial contribution to request from companies in order to support Fellowships for source country students, it was guided less by consideration of what would be a fair share of the financial benefits the companies might derive from selling varieties incorporating *Xa21*, and more by the amount that would be needed to cover the costs of visiting scholars at the University.

Professor Ronald has kept IRRI informed of her progress in setting up the Genetic Resources Recognition Fund, but did not consult representatives from potential source countries such as Mali during the process. Since the creation of the Fund, she has corresponded with Dr. Aboubacar Toure, head of Mali's Sorghum Breeding Programme, who is Director-General of the University of Mali. Dr. Toure contacted Professor Ronald to say that he could propose

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<sup>40</sup> Personal communications with Prof. Ronald 18 February 1998 and Prof. Barton, 19 February 1998.

<sup>41</sup> Personal communication with Prof. Ronald 18 February 1998.

<sup>42</sup> Personal communication with Prof. Barton, 19 February 1998.

students as candidates for Fellowships to be sponsored by the Fund. Professor Ronald has said that she will be in touch with him if either of the companies commercialises any product including *Xa21*, at which point money will be paid into the Fund to support Fellowships.

## CONTENT AND IMPLEMENTATION OF THE ARRANGEMENTS

### INPUTS

#### **Collection and exploration of resistance to rice blight in India**

Dr. Devadath of the Central Rice Research Institute (CRRI) in Cuttack, India obtained a sample of the Malian wild rice species *Oryza longistaminata*, and maintained the strain, then known as *O. barthii*, at CRRI under the accession number 12156-1. CRRI maintains a large collection of wild species of rice from around the world, and Dr. Devadath is a plant pathologist, specialising in the bacteria that colonise rice. As part of his research programme to find genetic materials that could be useful to develop varieties of rice resistant to blight, he tested the species for its resistance to various strains of the bacterium *Xanthomonas oryzae* pv. *Oryzae* ('Xoo'). In 1976, Dr. Devadath informed Dr. Khush, of the International Rice Research Institute (IRRI) in Los Baños, Philippines, that the strain had proven to be resistant to several strains of bacterial blight in India. Dr. Devadath distributed samples of the resistant strain of *O. longistaminata* to several research institutes in India, and, during a visit in 1977 to the Rice Research Institute of Rajendra Agricultural University (RAU) at Mithapur, Dr. Khush obtained a sample, which he took back to IRRI.

#### **Characterisation of *O. longistaminata*, breeding of IRBB21 and identification of *Xa21* by IRRI**

In 1977, Dr. Khush and his colleagues regenerated the sample he had obtained of *O. longistaminata*, multiplied the clone, and found it to be resistant to all six known races of bacterial blight in the Philippines. From 1978 to 1990, Dr. Khush conducted an intensive breeding programme, crossing and back-crossing *O. longistaminata* with the widely-used rice variety IR24, which is susceptible to rice blight. His aim was to transfer resistance to Xoo-induced blight from the landrace into the cultivated variety. The work was part of a programme in which IRRI researchers were introducing a series of pieces of genetic material coding for disease resistance (known as *Xa1*, *Xa2*, *Xa3*, etc.) into rice variety IR24. They called the resulting group of resistant varieties, each of which differed by a single gene for disease resistance, IRBB1, IRBB2, etc. The genetic material from *O. longistaminata* that coded for blight resistance was dubbed '*Xa21*'. Through a decade of traditional breeding, crossing and back-crossing *O. longistaminata* with IR24, the IRRI team learned that the resistance to blight was conferred by a small region of a single chromosome, and possibly even by a single gene - *Xa21* - which they had transferred to the cultivar IR24. The resistant variety of IR24 into which the IRRI team bred *Xa21* was called IRBB21.

#### **Isolation and cloning of the gene *Xa21* by the University of California, Davis**

In 1990, Pamela Ronald had just taken up a position as a postdoctoral fellow at Cornell University.<sup>43</sup> Intending to identify the location of *Xa21* in the rice genome, she obtained a sample of IRBB21 from IRRI. From a policy perspective, it is important to note that Professor Ronald obtained the materials prior to the entry into force of the Convention on Biological Diversity in 1993, prior to the 1994 agreements between the FAO and the Centres of the CGIAR, and prior to the use of material transfer agreements by IRRI. The implications of this situation are explored further in the conclusions section.

In 1992, having taken up a faculty position at UC Davis, Professor Ronald started work with colleagues at UC Davis to clone the length of genetic material now known as *Xa21* for further study. They knew that it was likely that *Xa21* was a section of DNA that encoded a protein responsible for blight resistance, but the challenge was to find the location of the small stretch of *Xa21* DNA in the entire genome of the variety. The genome of rice is complicated, some 100 times the size of that of the bacterium *Escherichia coli* (*e.coli*), whose genome has now been mapped, and some 15% of the size of the human genome.<sup>44</sup>

Using map-based cloning techniques developed by researchers for the human genome project, Professor Ronald and the UC Davis team characterised useful markers on the twelve rice chromosomes, examined over 1000 rice plants for occasions on which these DNA markers were revealed in conjunction with blight resistance, and, in 1995, after five years of work, identified and cloned *Xa21*.

*Xa21* has now been introduced into the DNA of a number of other rice varieties. The original host was rice variety Taipei 309, an old strain that is no longer grown, but is easily transformed and susceptible to Xoo. The transgenic Taipei 309 was tested against 31 different Xoo strains from eight countries, including India, the Philippines and Costa Rica. *Xa21* is now being introduced into several high yielding rice varieties.

In 1995, the “inventors”, Professor Ronald, Wen-Yuan Song and Guo-Liang Wang, filed a patent, held by UC Davis, on the *Xa21* gene sequence. In June 1996, in consultation with Professor Barton, UC Davis established the Genetic Resources Recognition Fund. In July 1996, UC Davis entered into an option agreement to license the gene to an agricultural biotechnology company, and entered into a similar arrangement with another company in January 1997. Each of these option agreements contains a clause that triggers a licensing agreement in the event that the company “commercialises”, or starts to sell, a product containing *Xa21*. One year after commercialisation of such a product, the first company will pay US\$52,000 and the second company US\$30,000, into the Genetic Resources Recognition Fund.<sup>45</sup> The Fund is to be used as a benefit-sharing mechanism. Any monies paid into the

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<sup>43</sup> While Pamela Ronald was a postdoctoral student, working for Prof. Steven Tanksley, she mapped the gene *Xa21* to chromosome 11, using a genetic map that had earlier been constructed in Prof. Tanksley’s lab. Personal communication with Prof. Ronald, 3 April 1998.

<sup>44</sup> Other grains, however, have even more complicated genomes. For example, that of wheat is five times the size of the human genome.

<sup>45</sup> While the benefit-sharing arrangements established by UC Davis with the two licensee companies each involves a single, lump-sum payment to the Genetic Resources Recognition Fund and this sum is not based on the payment of a royalty, Professor Ronald believes that, in the future, a share of royalties could be the basis of future arrangements between universities or research institutions and companies. With this in mind, she has provided the following “sample text ... that can be adapted to a particular institution for the purpose of setting up a Genetic Resources Recognition Fund”:

“In addition to other royalty obligations, company x shall annually pay n% of sales of products and derivatives of gene x as defined in Article X, into a genetic resources recognition fund for n years following the end of the first year of commercialisation, until it has transferred a total of US\$X into that fund under this agreement. The genetic resources recognition fund shall be maintained by the university as a separate restricted fund, to be

Fund if and when a company commercialises a product containing *Xa21* will be used to sponsor Fellowships at UC Davis for students from source countries such as Mali.

The agreements with the licensee companies do not contain specific terms enabling UC Davis to monitor the use of the genes during the research and development process within the companies, but it would be relatively easy for staff at UC Davis to tell whether any new product introduced by one of the licensee companies contained the *Xa21* gene. It is likely that the product would be marketed for the blight resistance for which the gene codes, and a sample of the product could easily be tested to see if it contained the gene.<sup>46</sup>

### **Further transformations and field trials on *Xa21***

Scientists in several institutions are now working on the time-consuming job of transforming *Xa21* into several useful rice varieties, such as IR64 and IR72, which are grown on about 22 million acres in Asia and Africa. The International Laboratory for Tropical Agricultural Biotechnology (ILTAB) based at La Jolla, California, is working on the transformation of *Xa21* into African varieties, and has already transformed *Xa21* into the high-yielding Chinese rice hybrid parent Minghui 63. Two field trials are underway to evaluate the morphology and yield of the resulting strain: one at UC Davis for transformed Taipei 309, and the other at the Chinese Academy of Agricultural Sciences in Hainan Province, China for transformed Minghui 63. The Rockefeller Foundation has sponsored field trials in China, and also a visit by a Chinese student from the Chinese Academy of Agricultural Sciences to ILTAB to learn how to perform the transformation of *Xa21* into the Chinese variety, and subsequently to UC Davis to be trained in the evaluation of the resistance of the new strain.

## **BENEFITS**

### **UC Davis**

UC Davis is receiving financial support from the two licensee companies to conduct a three-year basic research programme proposed by Professor Ronald which will investigate in more depth how the gene *Xa21* functions. The companies themselves are conducting more applied research. In addition to this research grant, the University, as holder of the patent on *Xa21*, together with the three named inventors, will receive undisclosed royalties from the companies if and when the companies commercialise a product containing *Xa21*.

### **The licensee companies**

In exchange for their sponsorship of Professor Ronald's further research on *Xa21*, UC Davis will transfer to the licensee companies the rights to exploit any commercial applications of the research that they are funding. The licensee companies also benefit from profits from sales of any products containing *Xa21* that they commercialise, following their research and development upon the material received from Professor Ronald. The licenses granted by UC

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used entirely for fellowship assistance to students and postdoctoral researchers from developing nations studying agriculture with a preference to be given to students and researchers from (name of source countries). The genetic resources recognition fund shall be managed by a Dean of the College of Agriculture and Environmental Science of the University of California at Davis."

(Ronald, Pamela C. 1998. The Genetic Resources Recognition Fund. AgBiotech News and Information. 1998 Vol.10 No.1 19N-22N.)

<sup>46</sup> Personal communication with Professor Ronald, UC Davis, 5 March 1998.

Davis to the companies are not exclusive. UC Davis is free to enter into similar arrangements with more companies, although each arrangement is likely to focus on distinct applications of *Xa21*, for example, its transformation into different crops.

### **Source countries**

Potential benefits to source countries under this model of benefit-sharing take two main forms. The first is access to the gene *Xa21*, a benefit that extends not just to individuals and institutions from source countries, but to all non-commercial researchers working on the gene and products incorporating it. UC Davis is making the gene *Xa21* available at cost price to non-commercial researchers, provided that they sign a material transfer agreement committing them to use the gene only for basic research and not to commercialise it. The material transfer agreement is available on the UC Davis Website. UC Davis thus intends that farmers in developing countries will be able to acquire seeds of UC Davis' transgenic lines at the same cost as traditional parent lines.

Under the terms of UC Davis' material transfer agreement, in the event that a researcher develops a commercial product from the gene, he or she will be obliged to enter into a separate licensing agreement with UC Davis, and to make a payment into the Genetic Resources Recognition Fund.

The second benefit for which some individuals from source countries may be eligible is sponsorship by the Genetic Resources Recognition Fund for a Fellowship at UC Davis. The Fund is dealt with under the section on 'Benefit-sharing mechanisms', below.

### **IRRI**

IRRI provided access to the sample of material from which *Xa21* was cloned, and, in return, in common with other researchers, has unrestricted access to the isolated gene *Xa21*. IRRI is able to transfer *Xa21* to its collaborators in national agricultural research systems around the world. Dr. Khush and his colleagues are now endeavouring to incorporate *Xa21* into many breeding lines, through a mixture of conventional breeding and genetic engineering. The resulting lines will be freely available, subject to IRRI's use of a material transfer agreement for materials from its breeding programme that are provided to the private sector.<sup>47</sup>

## **BENEFIT-SHARING MECHANISM**

### **Administration of the Genetic Resources Recognition Fund**

The Genetic Resources Recognition Fund is a separate, restricted fund established by UC Davis and managed by the Associate Dean of the College of Agriculture and Environmental Science. There are currently no monies in the Fund, as these will only accrue if the licensee companies commence sales of a product incorporating *Xa21*. When monies are paid into the Fund, the University plans to appoint a committee to select students. The plan is for the Committee to be composed of UC Davis staff, although Professor Ronald would like to involve representatives from source countries in the selection of students. Criteria for eligibility for Fellowships sponsored by the Fund have not yet been developed, but the current intention of the

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<sup>47</sup> Currently, only materials from IRRI's breeding programme that are sent to private companies are sent under a material transfer agreement (MTA). Improved materials are currently sent to National Agricultural Research Systems (NARS) without the use of an MTA. At present, MTAs are used routinely only for germplasm from IRRI's genebank collection. Personal communication with Dr. Michael Jackson, IRRI, 6 April 1998.

University is that IRRI scientists and students will not be eligible, although Filipino nationals could be eligible as the Philippines would be likely to be regarded as a 'source country'.<sup>48</sup>

### **Contribution to the Genetic Resources Recognition Fund**

Contributions to the Genetic Resources Recognition Fund will come from three sources: licensee companies, the University and the inventors.

Contributions to the Fund by licensee companies: The option agreements UC Davis signed with the two licensee companies each contain a clause that triggers a licensing agreement in the event that the company "commercialises" a product containing *Xa21*. Commercialisation is defined in each agreement as the commencement of sales. One year after each company first commercialises a product based on *Xa21*, it is to pay US\$52,000, in the case of the first company, and US\$30,000, in the case of the second company, into the Fund.

Contributions to the Fund by UC Davis: In a letter from the University's Vice-Chancellor of Research to Professor Ronald, the University has committed to making a payment into the Fund matching that made after the first year of commercialisation by the first licensee company. The money will come from the budget that the campus Chancellor has already dedicated to Professor Ronald's departmental budget. It is not yet clear whether the University will match any further contributions, whether from the second company or from any corporate partners commercialising products containing *Xa21* in the future. The University intends to review its policy on the Fund after the first payment into the Fund by a company. At this point it may amend its policy on requiring companies to pay contributions into the Fund, or it may commit to additional contributions in the future.

Contributions to the Fund by the inventors: Professor Ronald and her fellow inventors Wen-Yuan Song and Guo-Liang Wang will contribute to the Genetic Resources Recognition Fund an unspecified amount of the royalties they receive from the companies in the event of commercialisation. This contribution is voluntary, and not required by the terms of any agreement between the companies, the University and the inventors.

### **Payments from the Genetic Resources Recognition Fund**

When revenue from the licensing of *Xa21* is paid into the Genetic Resources Recognition Fund one year after commercialisation of a product, the University will identify the country or countries that should benefit from the fund, and select graduate or post-doctoral students from those nations to receive fellowships at UC Davis in various disciplines of agriculture. The University is considering ways in which some proportion of the work of Fellows supported by the Fund could be carried out jointly in the source countries themselves.

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<sup>48</sup> Personal communication with Professor Ronald, UC Davis, 5 March 1998.

**Table 1: Summary of the Inputs by and Benefits to the Major Actors in the *Xa21* case study**

	<b>IRRI</b>	<b>INVENTORS</b>	<b>UC DAVIS</b>	<b>LICENSEE COMPANIES</b>	<b>SOURCE COUNTRIES</b>
<b>INPUT</b>	<ul style="list-style-type: none"> <li>• identified <i>Xa21</i> and transformed it into IR24, (making IRBB21) and several other varieties</li> </ul>	<ul style="list-style-type: none"> <li>• isolated the gene <i>Xa21</i></li> </ul>	<ul style="list-style-type: none"> <li>• isolation of <i>Xa21</i> and its transformation into various high-yielding rice varieties</li> <li>• evaluation and field trials of transgenic rice varieties containing <i>Xa21</i></li> <li>• commitment to pay a sum matching the first payment by a licensee company into the GRRF</li> </ul>	<ul style="list-style-type: none"> <li>• applied research on <i>Xa21</i> to develop a commercial product</li> <li>• undisclosed financial support for three-year research programme at UC Davis</li> <li>• commitment to pay undisclosed royalties to UC Davis and inventors</li> <li>• commitment to pay US\$52,000 (first company) and US\$30,000 (second company) to the GRRF one year after the start of sales of any commercial product incorporating <i>Xa21</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>O. longistaminata</i> originated in Mali.</li> </ul>
<b>MONETARY BENEFITS</b>	(None)	<ul style="list-style-type: none"> <li>• undisclosed royalties from the licensee companies</li> </ul>	<ul style="list-style-type: none"> <li>• three-year research grant from two licensee companies</li> <li>• undisclosed royalties on sales of any product commercialised by licensee companies based on <i>Xa21</i></li> </ul>	<ul style="list-style-type: none"> <li>• prospective revenue from any products incorporating <i>Xa21</i> that may be successfully commercialised</li> </ul>	(None)
<b>NON-MONETARY BENEFITS</b>	<ul style="list-style-type: none"> <li>• access, at cost price, to cloned <i>Xa21</i> from UC Davis, and to transgenic varieties containing it.</li> </ul>	(None)	<ul style="list-style-type: none"> <li>• free access to blight resistant rice strain IRBB21 from IRRI, whose scientists had already identified <i>Xa21</i></li> </ul>	<ul style="list-style-type: none"> <li>• access to <i>Xa21</i> and the results of research sponsored at UC Davis</li> </ul>	<ul style="list-style-type: none"> <li>• Eligibility for Fellowships sponsored by the GRRF</li> <li>• Access at cost price to <i>Xa21</i> and transgenic varieties containing the gene for non-commercial purposes</li> </ul>

Professor Ronald is keen to link the Fund not just to *Xa21*, but to the licensing of any other genes on which the University works. The University has not yet defined its benefit-sharing strategy nor the criteria for selecting Fellows in any detail. Professor Ronald believes, however, that students may be selected from any developing country that is the origin of a gene which UC Davis licenses to companies. In the case of *Xa21*, the gene is probably only found in rice variety *O. longistaminata*. The specimen from which *Xa21* was isolated came originally from Mali, so Professor Ronald believes that students from Mali will be the first priority as potential beneficiaries from the Genetic Resources Recognition Fund. However, should the monetary benefits from licensing *Xa21* turn out to be considerable, Professor Ronald hopes that the benefits could be spread by using the Fund to sponsor students from more countries. The countries concerned could be other countries where *O. longistaminata* is found, but Professor Ronald hopes that, eventually, the Fund may receive payments for licenses of genes from several different countries. Although the situation is unlikely to arise for some time, in these circumstances Professor Ronald envisages a benefit-sharing mechanism that would be multilateral in nature, funding Fellowships for students from any of the source countries, rather than a strictly 'bilateral' arrangement, under which the exact value of license fees obtained for a gene from one country would sponsor students from just the country in question.<sup>49</sup>

## IMPACT ON CONSERVATION

Professor Ronald hopes that the use of *Xa21* will raise awareness of the utility of genes from wild species when they are introduced into improved varieties, and thus increase the appreciation of the importance of conservation by the public, students and companies alike.<sup>50</sup>

Regulations concerning field trials on rice strains containing *Xa21* have some bearing on the impact on conservation of introducing such strains. The trials at UC Davis are subject to regulations by the US Department of Agriculture which require environmental impact assessments, and which prescribe biosafety standards. For example, the new strains must be planted at a distance from other plants to avoid cross pollination, and strains containing blight cannot be tested, as the bacterium responsible for the blight is an organism that can only be used under special quarantine conditions. The field trials underway in China are subject to biosafety procedures regulated by the Chinese Ministry of Agriculture.

## CONCLUSIONS

### **Introduction**

This case study thus provokes two main questions. First, did the policy framework prevailing at the time when Professor Ronald obtained the sample of IRBB21 promote the fair and equitable sharing of benefits, and is it possible to assess the effects of the changes in policy that are currently under discussion in international fora? Secondly, is the voluntary approach to benefit-sharing adopted by UC Davis fair and equitable, irrespective of legal and policy requirements (or the lack of them)?

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<sup>49</sup> Personal communication with Prof. Ronald, UC Davis, 5 March 1998.

<sup>50</sup> Personal communication with Prof. Ronald, UC Davis, 5 March 1998.

Whatever the reader considers to be the answer to these two questions, it is clear that establishing the mechanism described in this case study, which appears to be the first of its kind, took considerable time and effort. As will become clear from the following discussion of the policy framework, UC Davis was under no legal obligation to share benefits. Professor Ronald's initiative was spurred purely by her personal conviction that it would be fair to establish some kind of benefit-sharing mechanism. Many universities around the world are engaged in the commercialisation of genetic resources in the field of plant genetic resources for food and agriculture (PGRFA), but few to date have taken the initiative to develop mechanisms for benefit-sharing.

In the field of pharmaceutical development, some form of benefit-sharing is relatively commonplace. Companies frequently pay a fee for access to samples and negotiate royalties with institutions providing them with genetic resources or value-added derivatives. Initiatives to promote the sharing of the benefits arising from uses of PGRFA, however, such as the Genetic Resources Recognition Fund described in this case study, are rare. The Fund established by UC Davis is a new concept, both to the university itself, and to the companies who have licensed the patented gene *Xa21*. There are few existing case studies on access and benefit-sharing mechanisms in the field of PGRFA from which researchers, genebanks and companies can learn. Prof. Ronald and her colleagues and advisors found themselves in a situation where they were effectively "making it up as they went along". Scientists conducting research on genetic resources face another challenge, in that they are generally unfamiliar with the finer points of access, benefit-sharing and intellectual property rights.

Despite the lack of experience, some advice is available. In this case, Professor Barton offered his expertise in law and policy. The key source of advice may come from those who will be affected by the proposed benefit-sharing mechanism. They can be consulted to ascertain whether proposed mechanisms would be regarded as fair and equitable, and can be involve in their design.

As countries and institutions focus on the access and benefit-sharing provisions of the CBD and the revision of the International Undertaking, more access and benefit-sharing initiatives are likely to arise. It would be helpful if these were documented to inform the international debate and to offer concrete assistance to others working in the area.

## **The policy framework**

- ***Access to PGRFA and benefit-sharing***

Professor Ronald acquired the sample of IRBB21 before the entry into force of the CBD, and prior to the 1994 agreements between the FAO and the Centres of the CGIAR and the use of material transfer agreements by IRRI and the other Centres. Consequently, the activities concerned in this case were largely unregulated, and the actors free to determine their own approach. In the future, however, the terms of access to genetic resources and sharing of benefits by universities such as UC Davis, genebanks and companies is likely to be increasingly shaped by access laws introduced by individual countries and by the terms of on access and benefit-sharing for PGRFA that results from the revision of the Undertaking.

According to the CBD, the regulation of access to genetic resources is a matter for each individual State. Countries are faced with a number of options for the way in which they choose to regulate access to PGRFA. They could do so on a bilateral basis, negotiating the terms of access with a particular user, such as a university, and requiring all benefits to be

shared with institutions within that country itself. Alternatively, they could choose to exercise their sovereignty by creating a multilateral system for access to PGRFA and benefit-sharing.<sup>51</sup>

- *Access to germplasm from the CGIAR Centres*

In the future, a revised Undertaking may clarify the terms of access to germplasm from the Centres of the CGIAR, and for sharing the resulting benefits. In the mean-time, it is interesting to speculate as to what would happen if a university wished to acquire a sample of IRBB21 from IRRI today. The breeding line IRBB21 does not appear to be ‘designated’ germplasm, and non-designated breeding lines are currently distributed by IRRI to organisations within National Agricultural Research Systems (NARS) without the use of material transfer agreements (and thus without conditions on access, benefit-sharing or intellectual property rights). This exemption is probably founded on the fact that universities, research institutes, genebanks and other organisations within NARS have traditionally been regarded as ‘academic’, ‘non-profit’ or ‘public interest’ institutions. However, there is a growing trend for these entities to engage in activities such as patenting and commercialisation. In these circumstances, it may be necessary for IRRI and other CGIAR Centres to expand their use of material transfer agreements to certain institutions within NARS if they are to prevent the type of monopolisation of genetic resources they appear to wish to avoid.<sup>52</sup> Such a move would need to weigh carefully the need for facilitated access to PGRFA, and avoid unwarranted cost and bureaucracy.

Changes may also be required to the provisions of the material transfer agreements used by the CGIAR Centres, since these currently refer only to constraints on the use of IPRs and transfer to third parties, and do not explicitly address other issues of central importance to the international debate, such as prior informed consent for certain categories of use of material and benefit-sharing. These issues will inevitably be addressed during the negotiations to revise the Undertaking.

- *IPRs*

The application of the global policy framework on intellectual property rights (IPRs)<sup>53</sup> to PGRFA remains a matter of controversy, as the call for a moratorium on IPRs on materials from the CGIAR indicates. None of the actors involved in earlier work to identify the blight resistance properties of *Xa21*, including IRRI, which had already identified *Xa21* and introgressed it into various other rice varieties, required any share of benefits as a condition for providing access to blight-resistant strains of rice. By patenting the gene, however, UC Davis alone among contributors in the research and development process put in place a mechanism to obtain monetary benefits for the subsequent commercial use of the gene. The field of crop development, where several different actors are frequently responsible for sequential contributions to the development of an end-product, poses a challenge to those aiming to design a system where each contributor obtains a fair share of the benefits.

IPRs are closely linked to the quantification of monetary benefits. For example, royalty payments are frequently tied to the duration of a patent. Patents are sometimes used to allocate

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<sup>51</sup> See, for example, ten Kate, K. and Lasen Diaz, C., 1997. The Undertaking Revisited: A Commentary on the Revision of the International Undertaking on Plant Genetic Resources for Food and Agriculture, in Review of European Community and International Environmental Law (RECIEL) Volume 6 Issue 3.

<sup>52</sup> See comments from Dr. Ismail Serageldin and Dr. Michael Jackson in the section on policy framework, above.

<sup>53</sup> The policy framework is provided by international agreements such as the Code on Trade Related Aspects of Intellectual Property Rights (TRIPS) and by national law on IPRs.

benefits among joint patent holders (for example, the co-authors of the patent on *Xa21*), and the desire to license rights from a patent holder often acts as the trigger for a benefit-sharing negotiation. However, as a policy instrument, the objective of an IPR regime is not to promote the sharing of the benefits arising from the use of PGRFA, and it generally does not do so. To achieve this objective, a range of other policy measures will be needed.

According to general principles of patent law, leaving aside the issue of how these principles are interpreted by patent offices and tribunals around the world, only inventions demonstrating novelty, non-obviousness and an inventive step are eligible for patent protection. Activities by researchers that fall short of these requirements are not patentable. Some regard current practice in interpreting patentability as a dangerous erosion of the distinction between true invention and a product of nature. In addition, there is an element of concern that the broad scope of some patents represents an unacceptable shift in the balance of the public policy ‘bargain’ between the temporary monopoly for inventors, and publication of innovations for the public good, and may restrict access to genetic resources. Interpretation of current practice of patent law and its effect on access and benefit-sharing will inevitably colour the interpretation of the clause contained in the FAO-CGIAR agreements and in the MTAs used by the Centres, which prohibits recipients of CGIAR material from seeking ‘any intellectual property rights over the germplasm or related information’. The promise by the CGIAR Centres in the FAO-CGIAR agreement not to take out IPRs on designated germplasm currently lacks clarity and is open to a number of conflicting interpretations. Recipients of designated germplasm from the CGIAR would benefit from clarification of the scope and nature of this obligation, which will attach to them through the material transfer agreements now in use by most Centres.

## **Objectives**

This case study demonstrates that, even if companies would not themselves have considered the issue of benefit-sharing and are not particularly enthusiastic about it, they are nonetheless prepared to make a commitment to share benefits if this is necessary to secure access to a gene which is of sufficient interest to them.

## **Process for establishing the arrangements**

Notwithstanding the voluntary nature of the benefit-sharing arrangement explored in this case study, some readers may question whether it results in a fair and equitable sharing of benefits. After all, UC Davis patented the gene *Xa21* and has decided unilaterally upon the nature of the benefits to be shared and on who may be eligible to share in them, without consulting the country from which the genetic resources were originally obtained (Mali).

While, in the future, the policy framework may provide more guidance for users of PGRFA through national access legislation, a multilateral system for access to PGRFA sanctioned by intergovernmental agreement of a revised Undertaking, or some mixture of the two approaches, some areas are likely to remain where there is no legal requirement or policy on access to genetic resources and benefit-sharing. For example, the sharing of benefits arising from the commercialisation of PGRFA currently held in private collections, whether held by universities, other ex-situ collections or companies, is unlikely to be a legal requirement. While benefit-sharing may not be compulsory in these circumstances, those entering into commercial arrangements can voluntarily involve source countries in the design of appropriate benefit-sharing mechanisms, including identification of potential beneficiaries and agreement over the kind of benefits to be shared.

In situations where the policy framework does not oblige specific action on access and benefit-sharing, but an institution or individual wishes to engage in voluntary benefit-sharing, one particularly difficult aspect of designing access and benefit-sharing mechanisms is deciding who is entitled to benefit. Should the beneficiaries be confined to nationals from communities local to where the specimen under investigation was obtained? To all nationals within the country concerned? To those within the “bioregion” (if the gene in question is found in specimens in neighbouring or other countries)? In this context of this case study, it is not clear whether *Xa21* may also be found in the future in *O. longistaminata* in countries other than Mali. However, Professor Ronald is considering the possibility of using the Genetic Resources Recognition Fund in the future to share the benefits arising from the use of any single gene on a multilateral basis, to sponsor students from any of the countries that have provided genetic resources upon which her team has conducted research.<sup>54</sup>

## **Inputs**

UC Davis was just one of a chain of actors, from RAU to CRRI to IRRI, without whose contribution the gene *Xa21* would likely never have been identified. However, the licensee companies are unlikely to have been interested in gaining access to the strains of rice developed by these actors which contained the gene. Instead, the companies were interested in licensing the gene sequence that resulted from Professor Ronald’s work.

## **Benefits**

The companies in this case did not wish to be contacted or identified. Thus it has not been possible to learn their objectives and opinions, nor to understand why they do not wish to be recognised. It is possible to speculate on a number of possible reasons for this reticence, but worth observing that some access and benefit-sharing arrangements have led to positive public relations for companies. The well-publicised partnership between the pharmaceutical company Merck and the Costa Rican institute INBio has received a mixed reception, but it is generally acknowledged that Merck received a great deal of positive publicity from the agreement. Indeed, the value of Merck shares rose after the agreement was announced. The company gained by being at the forefront of benefit-sharing in its sector. The licensees in this case are among the first to enter into benefit-sharing arrangements in the field of agriculture. It remains to be seen what kind of publicity this case will attract and what kind of feedback UC Davis will receive.

The companies have made a binding commitment to pay the agreed sums into the Fund one year after commercialisation in their option agreements with the UC Davis. The University’s own commitment takes the form of a letter from the Vice-Chancellor of the University to Professor Ronald, rather than forming part of the University’s contractual obligations in its agreements with companies. The University also has yet to decide whether it will make contributions to the Fund to match the US\$30,000 that will be made by the second company in the event of successful commercialisation, and indeed whether it will match payments to the Fund by any other companies who license *Xa21* or other genes in the future. Furthermore, according to UC Davis rules, it is a matter of personal choice for the individual inventors as to whether they decide to contribute to the Fund any of the royalty payments they will receive from the companies in the event of successful commercialisation.

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<sup>54</sup> See footnote 3, supra.

The degree of exclusivity of agreements for access to genetic resources has a bearing on what kind and level of benefits can be expected.<sup>55</sup> This factor needs to be taken into consideration in concluding whether arrangements with licensee companies are fair and equitable. If a company's right to commercialise a particular gene is tightly defined by specifying a particular use of a gene within a particular crop, the benefits that the company shares may be less than if it is entitled to exclusive use of the gene across many or all crops.

This case is a purely voluntary initiative, as described above. Another consideration when assessing the fairness of future arrangements concerning access to genetic resources may be the extent to which stakeholders were involved in determining the kind, value and timing of benefits, including whether the benefits are to be provided in kind by one of the actors (as in this case, where the benefit provided by UC Davis takes the form of education at UC Davis) and whether the choice of benefits is firmly fixed by one of the actors (as in this case study) or can be mutually agreed.

One interesting feature of this case is that the maximum value of benefits to be paid into the Genetic Resources Recognition Fund was determined by considering the costs of providing the kind of benefit that UC Davis decided to share, namely sponsorship of students at the University, rather than a proportion of the monetary benefits that would be obtained by the licensee companies (i.e. a ceiling was placed on the amount that the companies are to pay into the Fund, rather than the companies paying a certain proportion of all the monetary benefits they receive into the Fund.) It will be interesting to see whether individuals reviewing the case consider this to be a fair and equitable approach to benefit-sharing.

The development of new and improved varieties of crop often involves a large number of actors, not all of whom benefit from their contribution towards the development of a commercial product. In this case, UC Davis obtained a patent on *Xa21* and entered into arrangements for the sharing of monetary benefits with licensee companies. Other actors such as RAU, CRR1 and IRR1 contributed to the identification of *Xa21*, but have not obtained monetary benefits in this way. If a different result is considered desirable, it may be necessary to devise new benefit-sharing mechanisms, including public sector funding, to reward earlier contributors for their efforts in conservation and pre-breeding.

## **Conservation**

Where genetic engineering is concerned, the implications of access and benefit-sharing arrangements for conservation of biological diversity include the need to consider biosafety.

Since the benefit-sharing mechanism involved in this case does not entail the dedication of any monetary benefits to conservation, its contribution to the conservation of wild rice species such as *O. longistaminata* is indirect, through raising awareness of the importance of these genetic resources for future crop breeding efforts. While those who commercialise PGRFA rely to some extent upon the genetic resources and earlier research of other actors, the monetary benefits that arise from commercialisation will not meet the costs of conservation, so that funding from the public sector or other sources will be needed for this purpose.

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<sup>55</sup> The material transfer agreement that Professor Ronald will sign with academic researchers seeking access to *Xa21* states that “[t]he patent application and corresponding patents covering these materials have been exclusively licensed to a company in the United States, and accordingly, no commercial licenses or rights are available for these materials.” (UC Davis material transfer agreement, in the form of a draft letter, dated 1 January 1997, from Prof. Pamela C. Ronald to “Researcher”, UC Davis Website: <http://indica.ucdavis.edu/default.htm>.) However, this is only the standard language used by UC Davis in its material transfer agreements. UC Davis, is, in fact, free to license *Xa21* to other companies for applications other than those for which it has already entered into agreements. (Personal communication with Prof. Ronald, 23 March 1998.)

## **Lessons Learned**

According to Professor Ronald, one important lesson that she learned from her involvement with this case is to “find the right people to talk to”. Getting advice from legal and policy experts such as Professor Barton is essential for scientists grappling with the complex issues of access and benefit-sharing.

Another lesson, according to Professor Ronald, is the need to be persistent. The creation, from scratch, of a new benefit-sharing mechanism takes time and determination. It is likely to be new and unfamiliar territory to those, both within one’s own institution, and outside it, whose support is necessary for the approach to succeed. The process takes a considerable amount of time and effort.

According to Professor Barton, another important lesson is that, where benefit-sharing is a new concept, it is easier to introduce mechanisms if they fit with existing institutional structures and accounting procedures.

## **Replicability**

While private companies working on crop development would currently appear to have little incentive to engage in benefit-sharing activities, as these have not been required of them in the past, this may change in the future. Depending on the results of intergovernmental negotiations, as initiatives such as that by Professor Ronald proliferate and become better known, benefit-sharing activities of this kind may become best practice. Professor Ronald is just beginning to discuss UC Davis’ Genetic Resources Recognition Fund with the other campuses of the University of California. More broadly, other universities worldwide could use a similar mechanism, in consultation with stakeholders such as source countries.