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INTERNATIONAL SERVICE
FOR THE ACQUISITION
OF AGRI-BIOTECH
APPLICATIONS

CIAT Proprietary Property Audit

Review of Procedures and Selected Projects at CIAT
Regarding the Management of Intellectual Property, Technical Property and information,
primarily of Biotechnology Related Activities

I S A A A
INTERNATIONAL SERVICE
FOR THE ACQUISITION
OF AGRI-BIOTECH
APPLICATIONS

22 November 2000

R David Kryder
IP/TT, ISAAA
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INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS

22 November 2000

Dr. Joachim Voss
Director General, CIAT
AA 67-13
Cali, Colombia.

Dear Dr. Voss:

Independent Auditors' Report: CIAT Proprietary Property

I am pleased to send you the completed Audit of CIAT's proprietary property management, comprising intellectual property (IP) and technical property and information (TP), and the in-depth review of selected projects.

The Audit was designed to focus on selected parts of CIAT's activities and existing agreements and contracts related to IP/TP management as a way of providing a pragmatic basis for CIAT's future policy towards and management of IP/TP. To this effect, we also undertook a detailed paralegal freedom-to-operate review of a major project to illustrate the processes and highlight the complexities of current IP/TP issues.

The Audit was conducted by a team of professionals in various aspects related to IP/TPmanagement, contractual issues, institutional strategies and biotechnology, including an ISAAA retained attorney and several consultants for advice on specialized topics.

Nevertheless, the accompanying report excludes legal opinions, including but not limitedto freedom-to-operate opinions or opinions regarding the patentability of germplasm or any technology or invention.

Conducted from April to October 2000, the Audit consisted of a visit to CIAT by several members of the team, the review of critical documentation, and detailed discussions in person and by other means with a variety of CIAT staff and management. We relied on CIAT to compile and supply us with those agreements, related documents, and information that they have in force, whose terms included proprietary property related obligations and rights, and found the documentation from CIAT staff members to be timely, detailed, and comprehensive. We have been given free access to all necessary documentation and related information as well as to CIAT staff at all levels and functions.

During our Audit, we applied standards and interpretations of facts and statements that would generally be applied with the same rigor by proprietary property managers servicing public or private sector entities in a range of industrialized countries, particularly the USA, where statutory protection is well established. As a consequence,

we placed special emphasis on policies, strategies and management practices related to the inflow to CIAT of IP and TP; to the outflow from CIAT of IP and TP; and to the internal handling and use of IP and TP.

You will find a detailed analysis of your institute's current policies, procedures and agreements, and selected projects that have IP and TP components. We list the major findings in the Executive Summary and provide you with approximately 30 detailed recommendations to point out areas where CIAT may wish to strengthen or harmonize its overall policies and procedures. Certain recommendations are directly related to the projects we analyzed; the relevant department or project leaders may wish to follow-up on these in the near term. Finally, we discuss the findings and recommendations from the perspective of germplasm management, central management, agreements management, biotech component management, biotech product management, freedom-to-operate management, strategic risk management, and electronic data management.

Our major conclusions are:

1. During the Audit, we found no matter that violated or violates CIAT's Board approved policies, or current practices of the not-for-profit and educational research and development communities for international agriculture.

2. We are confident that no Audited activity, agreement, or policy and procedure of CIAT constitutes any impropriety.

3. The Audit demonstrated to us that CIAT management and staff are well aware of the challenges facing CIAT as it relates to IP and TP management, with an eagerness to build upon the institute's existing capacity in these areas.

4. We are certain that our in-depth analysis of several projects, particularly the freedom-to-operate review, will serve your objectives of establishing rational policies, consistent strategies and predictable management systems as they relate to IP and TP.

5. We are encouraging CIAT to move swiftly with a revision of its overall IP/TP policies once senior management and possibly the Board of Trustee have had an opportunity to review our detailed recommendations.

6. The above noted need for the harmonization of CIAT's policies and procedures with systematic and predictable IP/TP rights management practices is not without cost, either financial or political. However, failure to do so will, in the long term, adversely affect CIAT's relationship with its staff, its clients, its donors and non-CIAT collaborators.

7. A large number of recommendations are directly related to the projects we analyzed and we strongly encourage that the relevant department or project leaders follow-up on these in the near term.

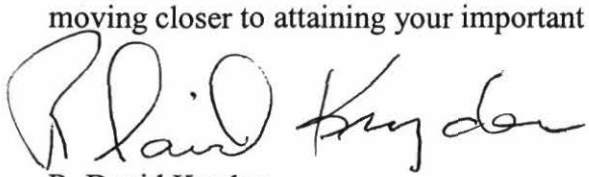
8. The Audit, which included a detailed analysis of a limited number of CIAT projects, should be taken only as a starting point for continuing reviews of IP/TP issues by CIAT staff, management and Board of Trustees. As the Audit report is integrated into CIAT's on-going activities, CIAT managers and staff members should be in a good position to have the in-house capacity to deal with the current recommended changes as well as proactively handle future IP/TP issues as they arise.

9. CIAT will then be in a good position to institutionalize formal and predictable IP and TP management procedures in a timely and effective manner. This will go a long way towards ensuring CIAT's effective operations in the future by allowing it to capitalize on IP/TP of others for the benefit of its clients.

In conclusion, allow me to stress that CIAT should neither fear nor fixate on the complexities of these issues. The management of proprietary property is nothing but a tool that, used wisely, will increase CIAT's efficiency and opportunities.

It is with pleasure that I acknowledge the contribution of a number of ISAAA staff, particularly Dr. Stanley Kowalski, ISAAA Interns in IP/TP Management, specifically Dr. Tantono Subagyo, and Dr. Reynaldo Ebora, and Dr. John Dodds of Dodds & Associates (ISAAA retained attorney), Donna Bobrowicz (consulting attorney) and Dr. Anatole F. Krattiger (international consultant, *bio*Developments LLC), for their dedicated hard work during the entire Audit and for their valuable contributions and advice.

I would also like to thank CIAT's management and staff for the excellent cooperation during the entire Audit and personally wish you and your institute every success in moving closer to attaining your important mission.



R. David Kryder
Director
Global IP/TT Initiative, ISAAA

CONTENTS

DISCLAIMER

The present document, while it contains information on ownership and statutory intellectual property rights issues, excludes legal opinions, including but not limited to freedom-to-operate opinions or opinions regarding the patentability of germplasm or any technology or invention.

EXECUTIVE SUMMARY

The Audit

An external Audit of selected procedures and projects at CIAT in regard to the management of Proprietary Property (PP, comprising intellectual property and technical property [IP/TP]), was conducted with emphasis on biotechnology-related activities and components, information management and germplasm movement, and an analysis of CIAT's management of the components. During the Audit, standards and interpretations of facts and statements were applied that would generally be applied with the same rigor by practitioners servicing public or private entities in industrialized countries.

The Audit was designed to focus on selected parts of CIAT's activities and existing agreements and contracts related to IP/TP and information management as a way of providing a pragmatic basis for CIAT's future policy towards and management of IP/TP and information. To this effect, we also undertook a detailed freedom-to-operate review of a major project to illustrate the processes and highlight the complexities of current IP/TP issues.

The Audit was conducted by a team of professionals in various aspects related to IP/TP management, contractual issues, institutional strategies and biotechnology, including an ISAAA retained attorney and several consultants for advice on specialized topics. Nevertheless, the accompanying report excludes legal opinions, including but not limited to freedom-to-operate opinions or opinions regarding the patentability of germplasm or any technology or invention.

Conducted from April to October 2000, the Audit consisted of a visit to CIAT by three members of the team, the review of critical documentation, and detailed discussions in person and by other means with a variety of CIAT staff and management. We relied on CIAT to compile and supply us with those agreements, related documents, and information that they have in force, whose terms included proprietary property related obligations and rights, and found the documentation from CIAT staff members to be timely, detailed, and comprehensive. We have been given free access to all necessary documentation and related information as well as to CIAT staff at all levels and functions.

Specific areas and questions considered for the projects and agreements included, among others:

- whether the purposes of the agreements were consistent with CIAT's stated institutional goals and objectives and in line with its status as an international organization;
- whether the strategies resulting from the obligations under the agreements to reach these objectives were consistent with CIAT's stated policies;
- whether key personnel were sufficiently knowledgeable about the obligations embedded in agreements to adhere to the intents that led to specific agreements;
- whether there are conflicts in research partnerships with non-CIAT partners regarding the use of CIAT-housed germplasm (e.g., Designated *vs*. Non-Designated) that may conflict with other CIAT – non-CIAT agreements (such as confidentiality);
- whether clear and consistent procedures are in place to implement and manage the obligations agreed to in certain agreements (e.g., confidentiality).

Major Conclusions

The major conclusions of the Audit are as follows:

1. During the Audit, we found no matter that violated or violates CIAT's Board approved policies, or current practices of the not-for-profit and educational research and development communities for international agriculture.
2. We are confident that no Audited activity, agreement, or policy and procedure of CIAT constitutes any impropriety.
3. The Audit demonstrated to us that CIAT management and staff are well aware of the challenges facing CIAT as it relates to IP/TP and information management, with an eagerness to build upon the institute's existing capacity in these areas.
4. We are certain that our in-depth analysis of several projects, particularly the freedom-to-operate review, will serve your objectives of establishing rational policies, consistent strategies and predictable management systems as they relate to IP/TP and information.
5. We are encouraging CIAT to move swiftly with a revision of its overall IP/TP policies once senior management and possibly the Board of Trustee have had an opportunity to review our detailed recommendations.
6. The above noted need for the harmonization of CIAT's policies and procedures with systematic and predictable PP rights management practices is not without cost, either financial or political. However, failure to do so will, in the long term, adversely affect CIAT's relationship with its staff, its clients, its donors and non-CIAT collaborators.
7. A large number of recommendations are directly related to the projects we analyzed and strongly encourage that the relevant department or project leaders follow-up on these in the near term.
8. The Audit, which included a detailed analysis of a limited number of CIAT projects, should be taken only as a starting point for continuing reviews of IP/TP issues by CIAT staff, management and Board of Trustees. As the Audit report is integrated into CIAT's on-going activities, CIAT managers and staff members should be in a good position to have the in-house capacity to deal with the current recommended changes as well as proactively handle future IP/TP issues as they arise.
9. CIAT will then be in a good position to institutionalize formal and predictable IP/TP and information management procedures in a timely and effective manner. This will go a long way towards ensuring CIAT's effective operations in the future by allowing it to capitalize on IP, TP and information of others for the benefit of its clients.

Specific Recommendations derived from the Analysis of Projects

Three current projects were analyzed in detail. These are:

- Product Clearance Review of Rice Hoja Blanca Virus Resistant Transgenic Rice

This deconstruction of a near-term product illustrated the process and highlighted the complexities and possible implications for CIAT in seeking to regularize its activities. CIAT will find itself in a position to consider the risks and rewards of not obtaining any further agreements for the components specified in a Product Clearance Spreadsheet prepared by the Auditors *vs*.

obtaining commercial licenses/agreements for each of the components *vs*. reconstructing the entire construct. Decisions regarding these approaches, or variants of them, may determine CIAT's success with the rice product and will have wider implications for other projects, specifically for NARS.

The project analysis led to seven recommendations related to the handling of IP, TP and related information, namely:

Recommendation 2: CIAT should institute a laboratory notebook protocol, particularly in electronic form (note that we included a special sub-section with a proposed policy for consideration by CIAT)

Recommendation 3: Setting-up of a Database and related management practices concerning the release of germplasm

Recommendation 4: Product Clearance Spreadsheet and FTO Information

Recommendation 5: Agreement management procedures

Recommendation 6: CIAT should clearly define its needs when negotiating and entering into MTAs with non-CIAT parties

Recommendation 7: Consider the establishment of an Office of General Counsel

Recommendation 8: Review and revise CIAT's standard MTA

Furthermore:

Recommendation 1: It might be worthwhile for CIAT to explore the patentability of CIAT's developed transformation system using immature panicles as this technique is being further developed. It appears that it involves innovative steps that are not yet fully covered by patents.

- *Brachiaria*

The analysis of this project centered around the complex area of movement of germplasm and terms under which germplasm moved to CIAT, within CIAT and to its clients, as well as to its collaborators (particularly the private sector). The major conclusions from this analysis are the following recommendations:

Recommendation 9: CIAT should designate a person responsible for monitoring developments under the CBD and FAO regarding FAO-designations

Recommendation 10: Review and possibly re-negotiate the agreement with Semillas Papalotla

Recommendation 11: Monitor and document the source of all germplasm used in breeding programs

Recommendation 12: Establish clear policies on negotiation with non-CIAT parties to ensure consistency and compliance

Recommendation 13: Set in place a strategic response plan in the event that contract violations are alleged

Recommendation 14: Institute a coordinated policy for germplasm movement between GRU and other CIAT units

- FloraMap™: A Tool for the Conservation of Genetic Resources

A detailed analysis of the development of FLoraMap™ led to the following recommendations:

Recommendation 15: CIAT should establish procedures for internally sharing essential research data

Recommendation 16: CIAT should establish procedures for receiving and sharing data from non-CIAT parties

Recommendation 17: CIAT should study the possible implication of selling products (such as FloraMap™ or seeds) on its tax-exempt 501 (c)(3) status.

Recommendation 18: CIAT should re-negotiate the agreement with ESRI or develop an alternative strategy

Recommendation 19: Future version of the FloraMap™ Manuals should be revised to include appropriate references to ESRI software

Recommendation 20: Harmonize distribution of FloraMap™ with CIAT's policy or adapt CIAT's policies to its current practices

Recommendation 21: CIAT should fully trademark the word "FloraMap" together with the corresponding logo to prevent being blocked from use by a non-CIAT party

Recommendation 22: CIAT should ensure that the type drawing trademark of "FloraMap" is in CIAT's name rather than in the name of one of its former Director General

Recommendation 23: CIAT should consult with its attorney and study the pros and cons of registering the copyright of FloraMap™ in countries where the product has potential value

Recommendation 24: CIAT should consider changing the licensing terms of FloraMap™

Recommendations based on an Analysis of CIAT's Current IP/TP Management Practices

A detailed discussion on the implications of the Audit findings is presented in Section 3 of the report. In essence, it is apparent that CIAT, at all levels, is doing a commendable job with the unnerving task of functioning under the new and evolving rules that are coming into play. Staff members, whether in support areas, management functions or in research were universally concerned to learn more about PP rights management. Throughout the organization there is a general spirit of willingness to "learn the new rules" in order to continue to move CIAT, in more efficient ways, toward its goal, and even to capitalize on these changes in a constructive manner. Certain areas where CIAT is harmonizing its internal policies with changing PP rights management realities are noted and discussed. These include:

- The Audit: Policy, Management and Procedural Implications

  Recommendation 25: CIAT should institutionalize a central IP/TP management office to oversee all aspects of in-licensing and out-licensing

  Recommendation 26: CIAT should establish formal internal procedures for the handling of all aspects related to IP/TP management

  Recommendation 27: CIAT should offer IP/TP management training to its staff

Recommendation 28: Following CIAT's analysis of the Audit, the Center should conduct a comprehensive review of all of its policies related to IP to ensure harmonization and consistency.

- Germplasm Management
  Recommendation 29: CIAT should review its policies and procedures related to the use and transfer of germplasm, and to the management of information derived thereof

- Central Management
  Recommendation 30: CIAT should formalize its various procedures affecting IP/TP management, ranging from confidentiality to staff and client training

- Agreements Management
  Recommendation 31: CIAT should harmonize its policies and procedures, and formalize its management, of its agreements

- Biotech Component Management
  Recommendation 32: CIAT should ensure that certain terms used in agreements are clearly defined and that the implications of standard definitions are properly understood

- Biotechnology Product Management
  Recommendation 33: CIAT must consider the implications of various options related to Freedom-To-Operate and should establish and communicate its position and mode of operation

- Electronic Data Management
  Recommendation 16: CIAT should establish procedures for receiving and sharing data from non-CIAT parties

Conclusion

It cannot be over-emphasized that CIAT should neither fear nor fixate on the complexities of these issues. The management of proprietary property is nothing but a tool that, used wisely, will increase CIAT's efficiency and opportunities.

CIAT's goal is not now and has never been in doubt. Effective IP/TP management has the potential to make its endeavors more effective. In a certain way, CIAT has no option but to deal with the IP issues since the rules have changed. The challenge for CIAT now is to continue on its path and reinforce its measures and activities to change, to better understand the new rules, and to capitalize on them for the benefit of the resource poor farmers it serves.

LIST OF RECOMMENDATIONS

LIST OF ABBREVIATIONS AND ACRONYMS

aphIV	hygromycin phosphotransferase gene
BoT	Board of Trustees
CAMBIA	Center for the Application of Molecular Biology to International Agriculture
CaMV	cauliflower mosaic virus
CBD	Convention on Biological Diversity
CD	Compact Disc
CDNA	Complimentary DNA
CGIAR	Consultative Group on International Agricultural Research
CIAT	International Center for Tropical Agriculture Centro Internacional de Agricultura Tropical
CNPGC	Centro Nacional de Pesquisa de Gado de Corte
DCW	Digital Charts of the World
EMBRAPA	Empresa Brasileria de Pesquisa Agropecuaria
ESRI	Environmental Systems Research Institute
FAO	Food and Agriculture Organization
FIRA	Federal Information Reform Act
FOIA	Freedom of Information Act
FTO	Freedom-to-Operate
GATT	General Agreement on Tariffs and Trade
GIS	Geographic Information Systems
GRU	Germplasm Resources Unit
IARC	International Agricultural Research Center
IFPRI	International Food Policy Research Institute
IIML	Integrated Information Management Laboratory
IP	Intellectual Property
IPGRI	International Plant Genetic Resources Institute
IRRI	International Rice Research Institute
ISAAA	International Service for the Acquisition of Agri-biotech Applications
MTA	Material Transfer Agreement
N	Nucleoprotein gene of RHBV
NARS	National Agricultural Research Systems

NGO	Non-Governmental Organization
Nos	Nopaline Synthase
PCR	Polymerase Chain Reaction
PCT	Patent Cooperation Treaty
PP	Proprietary Property (comprising IP and TP)
RHBV	Rice hoja blanca virus
ROM	Read Only Memory
SAMMDATA	South American Monthly Meteorological Data
SGRP	CGIAR System-Wide Information Network for Genetic Resources
TFP	Tropical Forages Program
TP	Technical Property
TRIPs	Trade-Related Aspects of Intellectual Property
UPOV	The International Union for the Protection of New Varieties of Plants Union Internationale pour la Protection des Obtentions Vegetales
USAID	United States Agency for International Development
USGS	United States Geological Survey
WIPO	World Intellectual Property Organization
WHO	World Health Organization
WTO	World Trade Organization

1. BACKGROUND AND INTRODUCTION

1.1 Proprietary Property Management at CIAT

Since its inception in October of 1973, the Centro Internacional de Agricultura Tropical (CIAT) has been an advocate for the poor in developing countries. Its focus was initially on Latin America, but has subsequently broadened to include other regions. A main strength of CIAT has been its ability to freely receive and distribute improved germplasm and related information, ranging from agronomic knowledge to plant breeding systems. In fact, this free flow of material and related information has been used by many of CIAT's funding sources as a performance measure. Understandably, CIAT staff and scientists—as well as the system of the Consultative Group on International Agricultural Research (CGIAR) as a whole—place a high value on the free exchange of information and material.

With the rapid expansion of biotechnology into the plant world, particularly since the early-1990s, it became apparent that this open approach was not sustainable if CIAT wanted to ensure that its clients continued to have access to the best germplasm incorporating the most valuable advances in science and technology. As increasing discoveries were made by the public sector in industrialized countries and with huge R&D investments by the private sector (both of which led to many patents in plant biotechnology), much of the technology was no longer freely available to CIAT. Furthermore, many of the new breeding and information technologies now commonplace in industrialized countries are out of the reach of CIAT because of the high investment requirement which is simply not available to the international agricultural research centers at times of declining budgets. (A single ag-biotech company in the USA, for example, may annually invest more into plant biotechnology R&D, including genomics, than the entire budget of the CGIAR system!).

What has been a traditional partner in research for the CGIAR—the universities—have also become constrained by funding and IP. The university community has also become more and more secretive about their research projects and very often is seeking intellectual property (IP) protection on their discoveries. Statutory protection became commonplace as institutions, using a mix of patent and plant variety protection laws, began to protect their biotechnological discoveries in order to recover their enormous research investments. Biotechnological components and germplasm resources became concentrated in the hands of fewer and fewer organizations. For the most part, particularly in the area of biotechnological discoveries, the dominant organizations were in the private sector and their vision did not focus on the world's poor for simple pragmatic or commercial reasons.

The CGIAR also began to study the effect of biotechnology on its system. The first endeavor was in 1989 when the World Bank convened a meeting in Canberra, Australia. But it was only in the mid-1990s when the CGIAR set-up two panels, one focusing on how the Centers could fulfill their international mandate from the scientific and technical perspective; the other focusing on implications of the increasingly proprietary nature of biotechnology. In its report, the latter panel recommended that the CGIAR develop expertise to manage technology transfer and IP issues, that current technologies used by the Centers be reviewed, and that the Centers' existing guiding principles on IP be reviewed, revised, formalized, and enforced. The principal recommendation,

the two panel reports concluded, was to ensure that the benefits of CGIAR research would continue to be delivered efficiently to their clients.

Over 10 years ago, CIAT launched its own biotechnology unit (although it had practiced tissue culture, isozyme screening, anther culture, and embryo rescue for quite some time). CIAT biotechnology researchers, working with external entities, have obtained materials and related information from outside sources. A great part of this assistance, granted to CIAT under restrictive conditions through material transfer agreements (MTA), was proprietary to the donor in the form of technical property (TP) rights.

In addition to the claims of TP rights in the donated materials and related information, much of such transferred material and related information came to CIAT with the donor's IP claims, typically in the form of patents or patent applications, already in place. Receipt of such protected materials and related information induced CIAT to institute certain restrictions on confidentiality, review its publication procedures, modify its processes for the release of CIAT-held germplasm, and seek a clearer path forward regarding CIAT's use of and the progeny of donated materials and related information for later release to CIAT clients. In order to chart a path forward, CIAT Management commissioned a comprehensive review of IP management issues. This IP management review was projected to consist of three parts:

1. obtaining an IP Audit;
2. developing a strategy for regularizing CIAT's use of non-CIAT technology; and
3. establishing long-term IP management guidelines.

Developing a sound IP management policy and strategy is not an easy matter, whatever the type of organization involved. In essence, however, IP management is nothing more than a matter of risk management. No one ever definitively knows who has rights to do what with all IP. This is partly the statutory protection area is in continual flux because with new patents continually being issued, older patents expiring, and patent-related court settlements taking place around the world. Also, due to the increasing complexity of the underlying sciences, courts and judges/juries have increasing difficulty in making consistent decisions. This is not unusual in newly emerging technologies and partly the reason the appeal process.

All that organizations can do is try to comply with the freedom-to-operate (FTO) opinions that they commission, establish protocols to defend (or proactively fight) their decisions and choices, and seek whatever licenses they believe that they need to reach their goals.

For an institution such as CIAT, licensing issues are further clouded because CIAT clients are from many different countries. Thereby the statutory protection laws required for full FTO are as varied as the CIAT client list. Also, although a few client countries permit some form of patenting of plants and plant parts/products, most do not permit this form of IP protection. Most CIAT client countries have some laws regarding plant variety protection (PVP) and most have some of the TRIPs protocols in place. Most client countries assure some form of TP rights protection based in contract law, but these rights are not universally enforced. Further, many client countries are extremely limited in their IP management knowledge or capacity.

This leaves CIAT with the challenge as to whether or not to distribute improved germplasm with full FTO or to pass this responsibility for obtaining FTO, along with CIAT's improved germplasm, on to the client country with a caveat regarding these matters.

Domestic consumption *vs.* export becomes another significant issue for CIAT as it reviews its client's needs. This is especially true for transgenic crops. Domestic consumption *vs.* export affects not only Proprietary Property (PP) management by CIAT and by the CIAT clients (whereby PP is defined as comprising intellectual property (IP) and technical property (TP) and related information; see page 4 for a detailed definition of these terms), but moves over into the areas of biosafety and international trade.

Hence many of the decisions that will lead an organization such as CIAT to seek commercial licenses (whether they are royalty-free or not) must flow from a strategic plan aimed at developing and/or maintaining clear relationships with the private sector while at the same time offering CIAT clients—the national agricultural research programs (NARSs)—products that they can freely deploy. The challenges of charting a clear path among the reefs of PP rights, biosafety, farmers' rights and international trade matters are not insignificant. Yet, the importance of offering clear direction in this storm is what is being asked of CIAT and the CGIAR system overall.

1.2 Conduct of the Audit

CIAT is one of the sixteen CGIAR centers. It has been conducting research with non-CIAT proprietary material and related information for a long time. With the significant changes that have taken place in the statutory protection environment during the last decade, CIAT is now seeking to protect its ability to freely distribute the products and services emanating from its research programs.

As a first step, CIAT began documenting the IP or TP rights to the material and information that is being used in its laboratories or is being created by its efforts. CIAT is further trying to determine the IP or TP rights that are attached to material and information that has been obtained from external sources. These efforts are giving CIAT a clearer understanding of the complexities of these rights and how CIAT might strategically deal with these matters in the future.

These objectives are to be achieved through a three-pronged approach:

1. conducting a comprehensive IP Audit by:
   a. identifying the major IP components used or handled by CIAT, whether the IP is formal or informal;
   b. identifying who owns the IP and/or was responsible for its creation;
   c. identifying the source of the IP;
   d. identifying any restraints on the use, protection, or development of the IP that may affect CIAT's ability to access, use, or distribute its own IP or non-CIAT IP;
   e. assessing the importance of the IP to CIAT's activities; and
   f. identifying all new IP being developed at CIAT

2. identifying a strategy for regularizing non-CIAT IP currently used by CIAT researchers, and
3. developing long-term IP management guidelines

The Center commissioned the International Service for the Acquisition of Agri-biotechnology Applications (ISAAA) to conduct an IP Audit (Audit) to specifically address issues related to point "d" (above) for certain specified CIAT projects and prepare an overall discussion on items 2 and 3 (above).

The projects for in-depth analysis were determined by consultation between the Auditors and the Center's Management and the choices were based on including a cross section from several programs that would highlight some of the generic IP-related issues while providing CIAT management with a detailed feed-back on some of its current challenges. These projects were:

- product clearance review of rice Hoja blanca virus resistant transgenic rice
- activities with *Brachiaria* and potential limits on distribution of improved germplasm
- the FloraMap™ tool for the conservation of genetic resources

Hence the Audit was designed to focus on selected parts of CIAT's overall activity and to:

- lay the groundwork for capacity building regarding IP/TP management within CIAT
- provide a pragmatic basis for CIAT's decisions regarding future policy changes

These "selected parts" of CIAT's overall activity were selected based on the following criteria:

- highly complex projects were preferred to fairly simple ones;
- activities that included the transfer of technology to CIAT;
- projects with products for transfer to NARS were given preference; and finally,
- projects with controversial issues were also preferred as a way of ensuring that CIAT receives the necessary guidance to formalize its IP strategy and policy.

More specifically, CIAT and the Auditors agreed:

- "Audit" shall mean the activity of ISAAA to produce an analysis of the PP of the Projects (in the case of the FloraMap™, the Audit was limited to Argentina, Bolivia, Brazil, Columbia, and the United States of America) in order to identify and list the Components of each Project, CIAT's management of those Components, issues surrounding the Components, and to prepare a profile of the known statutory limitations affecting the Components.
- "Findings" shall mean a written compilation of the Components based on information provided by CIAT, a discussion of ISAAA's investigation, and a letter to CIAT's management.
- "Component(s)" shall mean the subdivisions of the Proprietary Property of the Projects.
- "Intellectual Property" shall mean, without limitation, intellectual property rights, including patent rights, plant variety protection certificates, unpublished patent applications, and any inventions, improvements, and/or discoveries that may or may not be legally protectable,

including all know-how, trade secrets, research plans and priorities, research results and related reports, statistical models and computer programs and related reports, and market interests and product ideas.

- "Technical Property and Information" shall mean, without limitation, computer software, germplasm and the biological materials and derivatives thereof, and related information.
- "Proprietary Property" is Intellectual Property and Technical Property and Information.

The Audit essentially began in March 2000 with CIAT providing the Auditors with certain project documentation. This was followed by an on-site visit to CIAT by three senior Auditors in April and included detailed staff interviews.

The Audit team is comprised of five IP Specialists in Plant Biotechnology and Patent Law, who include R. David Kryder, the Director of ISAAA's Global Intellectual Property & Technology Transfer Initiative, Dr. Anatole F. Krattiger (initially as ISAAA's Executive Director and later as international consultant with *bio*Developments, LLC), Donna Bobrowicz (a patent attorney retained by ISAAA), Dr. Stanley P. Kowalski, a biochemist, and Dr. John Dodds of Dodds & Associates, a law firm specializing in IP that has been retained by ISAAA. In addition, significant support has been provided by two ISAAA IP Interns.

A confidentiality agreement between CIAT and ISAAA was executed to cover all aspects of the Audit prior to entering into initial discussions. During the course of the Audit, ISAAA retained the services of several additional attorneys and consultants regarding topics of specific advice and opinion. It should be noted that ISAAA has confidentiality agreements in place, as a condition of retention with all non-ISAAA attorneys and consultants. Confidentiality also binds all ISAAA employees and Interns, as a condition of their employment or Internship.

The Auditors are grateful for having been given free and timely access to CIAT senior management, researchers, documents, and related information as it was requested.

2. REVIEW OF AGREEMENTS AND PROJECTS

2.1 Product Clearance Review of Rice Hoja Blanca Virus Resistant Transgenic Rice

2.1.1 Rice Hoja Blanca Virus (RHBV) Resistant Transgenic Rice

Rice and beans have been, and continue to be, of critical importance to the dietary requirements of millions of people throughout Latin America. The extraordinary rate at which rice production has increased in this region over the past few decades is indicative of this trend:

- rice production has doubled between 1966 and 1995
- wetland rice yield increased from 3.3 to 4.6 tons (5.0 for irrigated rice)/hectare between 1966 and 1995
- hectares planted to rice have increased from 5.8 to 6.7 million

This increased production, sustainability and availability of rice have been particularly important to the many resource-poor farmers, as well as urban poor, throughout the region.

Rice breeding and varietal development have been important factors in the steady increase in production. Over the past 30 years, over 300 new varieties have been released in Latin America. With nearly 120 of these varieties originating from crosses made at CIAT, it is transparently obvious as to CIAT's crucial and continuing contribution to rice agriculture in the region.

CIAT has been involved in the development of pest and disease resistant rice through traditional plant breeding strategies. However, recent advances in genetic engineering have permitted traditional plant breeders to join with biotechnology researchers to project possibilities for other, very significant means to reduce rice losses due to environmental stresses, pests and diseases. To this end, researchers at CIAT have been actively developing transgenic rice with durable resistance to rice hoja blanca virus (RHBV). RHBV is a tenuivirus, with a divided ssRNA negative sense genome. It is a major viral disease agent of rice throughout the Caribbean region, central and northern Latin America. RHBV is transmitted by leafhoppers (*Tagosodes orizicolus*), which are also negatively impacted by the virus. RHBV is transmitted in a persistent, circulative manner, characteristically with sporadic severe epidemics followed by hiatuses wherein the RHBV levels are low. Major outbreaks have been reported to cause up to 80% yield reductions

Breeding programs have developed rice varieties with partial resistance to RHBV. However, these lines provide inadequate defense since plantlets younger than 25-days-old display significant susceptibility to the virus. To help plug this portal of susceptibility, and augment the already existing sources of resistance, CIAT has undertaken a project to genetically engineer the RHBV nucleoprotein (N) gene into the rice genome. Rice transformed with this gene display significant reduction in disease development when challenged with RHBV, relative to susceptible controls. RHBV resistance of this transgenic rice is mediated by the viral N gene cloned in the sense direction. The N gene is on the virus complimentary strand of RNA 3. The N protein is predicted to consist of 319 amino acids with a molecular mass of 35,336. The resistance mechanism in transgenic rice was thought to be a type of coat protein-mediated cross

protection. By eventually introgressing this gene(s) from the transformed rice into rice varieties which already express the endogenous resistance phenotype, i.e., bred-resistance, a "pyramiding" of resistance factors may well ensure stable, durable resistance throughout the rice plant's entire period of growth, from planting to harvest.

The project, funded in part by the Rockefeller Foundation's International Program on Rice Biotechnology, is fairly well advanced. However, as CIAT researchers are proceeding with their product development work, CIAT management is looking at related IP and TP issues. IP rights issues center on statutory protection rights (patents, Plant Variety Protection certificates, copyrights, etc.) while TP rights are concerned with the ownership of tangible materials used in research.

Prior to CIAT transferring the improved, RHBV N gene containing rice germplasm to its clients, CIAT is seeking to establish its duties and obligations through a PP Audit of the RHBV Resistant Transgenic Rice Project. The Auditors have conducted an extensive deconstruction of various components of the project that details information about this transgenic product's various components. With this information, a CIAT patent attorney will be able to produce a freedom-to-operate opinion ("FTO") to guide CIAT management regarding risks related to releasing improved transgenic RHBV nucleoprotein gene transformed rice. Such a FTO opinion will include a review of biotechnology components and germplasm as well as those licenses that impinge on the project.

Detailed knowledge of CIAT's PP rights and obligations are critical for several reasons. First, CIAT will wish to maintain its reputation for ethical behavior. Second, because client (farmers, researchers, private companies, NARS, general public) capacity building is one of CIAT's major goals, CIAT ought to consider instituting model PP rights management systems to be able to share its experience with NARS and other clients. Finally, because CIAT's current strategy includes developing collaborative research and/or commercial licensing activities with a variety of non-CIAT laboratories (public and private), CIAT will need to establish its capability to properly manage PP related matters for all projects, not just the RHBV Resistant Transgenic Rice Project.

2.1.2 Deconstruction

The overall scheme for a deconstruction process for the RHBV Resistant Transgenic Rice Project is presented below. This deconstruction process divides the germplasm and biotechnology aspects of a product into nine main components and fifteen sub-components:

- plant/seed source
- cloning vectors and process
  - pBS (Stratagene System)
  - cDNA synthesis
- gene construct(s)
  - pRT101

  - PGSFR761A
  - pVR3
- Selectable marker gene expression cassette
  - hygromycin resistance gene (*aph IV)*
  - CaMV 35S promoter
  - Nos terminator
- RHBV resistance gene expression cassette
  - nucleoprotein (N) gene
  - CaMV 35S promoter
  - Nos terminator
- transformation method
- plant tissue culture and regeneration
- viral coat protein mediated cross protection
- screening/molecular analyses
  - PCR analysis
  - *Taq* polymerase
  - DNA sequencing
  - other laboratory techniques and procedures

Deconstruction was done by way of the Auditors posing a series of questions that seek to name and identify the source of each of the components and sub-components. Then the PP rights that are potentially attached to each component and sub-component were identified. This deconstruction activity is realized by querying the RHBV Resistant Transgenic Rice Project researchers, by searching various science and patent databases, and by analyzing agreements that CIAT has executed with non-CIAT sources. Results are entered into a RHBV Resistant Transgenic Rice Project Product Clearance Spreadsheet given in Table 1 (see also Appendix 1).

This Product Clearance Spreadsheet is a confidential document that becomes the basis of a patent attorney's formal FTO opinion. The FTO is typically secured under attorney-client privilege. Further, the Product Clearance Spreadsheet and the FTO opinion ought to be regularly (at least annually and as the statutory protection landscape changes) reviewed by CIAT management. Finally, all of these documents should be classified as "CIAT CONFIDENTIAL" and ought to be circulated on a need-to-know basis only.

With a regularly-updated FTO in hand and administrative systems in place that provide on-going PP management, CIAT will be able to produce and regularly revise a Product Clearance Profile that was produced for the RHBV Resistant Transgenic Rice Project by the Auditors (Table 2). It must be noted that this Product Clearance Profile is preliminary and was developed without benefit of a legal FTO opinion or a complete review of all of CIAT's agreements with non-CIAT parties.

Table 1. Product Clearance Spreadsheet for Hoja blanca virus resistant transgenic rice

Note that the list of possible applicable patents in this table is not a legal document and will require verification by CIAT's legal counsel

Protocol/ Materials	Patent No[a]	Title	Inventor(s)	Assignee	Filing Date	Issue Date[b]	Source and/or Licensing Requirement(s)
1. Plant Source							
Rice	Cultivar Name: CICA 8, Country of Origin - Colombia, FAO in trust, Accession Identifier, IRRI-IRGC-53078 , Common Name - Rice, Scientific Name - *Oryza sativa*[c]						
2. Plasmid Construct							
pVR3	The following plasmid constructs were used in the construction of pVR3: **pRT101**-the Kpn I - Sst I fragment containing the 1.4 Kb R3-C8 clone was inserted in this plasmid in the sense direction between the CaMV 35S promoter and Nos terminator. The fragment of clone R3-C8 was previously cloned in pBluescript KS+ (Stratagene). **pGSFR761A** - the 2.3 kb hygromycin B phosphotransferase gene cassette driven by CaMV 35S promoter was inserted into pBS(+) (Stratagene) and designated as **pBS hygromycin**. The CaMV 35S-N gene-Nos cassette was then transferred to **pBS hygromycin** to create **pVR3**.						
Stratagene Corporation: pBS(+) was used in the construction of **pBS hygromycin** and subsequently with **pVR3**	US5128256	DNA cloning vectors with in vivo excisable plasmids.	Huse et al,	Stratagene	20-Apr-89	7 Jul 92	Note:pBS, except its multiple cloning site is almost identical to pBluescript which is a component of Uni-Zap vector. The Uni-Zap XR vector is covered by this US patent owned by Stratagene which specifically prohibits any offer for resale, distribution or transfer to any third party. Use for research purposes only. The same applies to US5286636,WO880508, EP 0286200

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Protocol/ Materials	Patent No[a]	Title	Inventor(s)	Assignee	Filing Date	Issue Date[b]	Source and/or Licensing Requirement(s)
	US5188957	Lambda packaging extract lacking beta-galactosidase activity	Short and Kretz	Stratagene	26-Feb-91	23-Feb-93	
	US5286636	DNA cloning vectors with in vivo excisable plasmids.	Huse et al.	Stratagene	21-May-92	15-Feb-94	
	EP0286200	DNA cloning vectors with in vivo excisable plasmids.	Sorge et al.	Stratagene	12-Jan-88	12-Oct-88	
	WO8805085	DNA cloning vectors with in vivo excisable plasmids.	Huse et al.	Statagene	12-Jan-88	14-Jul-88	
pRT101							pRT101 and PGSFR761A were brought to CIAT by Dr. Jorge Mayer from Max Planck Institute and Plant Genetics Systems respectively. There is no Material Transfer Agreement or other documentation attached.
pGSFR761A							
3. Promoters	(CaMV 35S-2, CaMV 35S, CaMV with 2x enhancer?)						
	US4407956	Cloned cauliflower mosaic virus DNA as a plant vehicle	Howell	The Regents of Univ. of California	13-Mar-81	4-Oct-83	
	US5352605	Chimeric genes for transforming plant cells using viral promoters	Fraley et al.	Monsanto Co.	28-Oct-93	4-Oct-94	
	US5858742	Chimeric genes for transforming plant cells using viral promoters	Fraley et al.	Monsanto Co.	24-Jun-96	12-Jan-99	
	US5550318	Methods and compositions for the production of stably transformed, fertile monocot plants and cells thereof	Adams et al.	Dekalb Genetics	9-Aug-90	27-Aug-96	
	WO8402913	Chimeric genes suitable for expression in plant cells	Fraley &Rogers	Monsanto Co.	16-Jan-84	2-Aug-84	
	US5322938	DNA sequence for enhancing the efficiency of transcription	McPherson & Kay	Monsanto Co.	17-Nov-92	21-Jun-94	
4. cDNA Synthesis (1.4kb cDNA clone R3-C8 derived from the 3' region of the Colombian isolate of RHBV RNA3)							
	US5668005	Cloned genes encoding reverse transcriptase lacking RNASE H activity	Kotewicz & Gerard	Life Technologies	12-Mar-96	16-Sep-97	

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Protocol/ Materials	Patent No[a]	Title	Inventor(s)	Assignee	Filing Date	Issue Date[b]	Source and/or Licensing Requirement(s)
5. Selectable marker gene (hygomycin phosphotransferase B , aphIV)							
	US5668298	Selectable marker for development of vectors and transformation systems in plants	Waldron C.	Eli Lilly and Co. (Applicant)	7-Jun-95	16-Sep-97	Almost identical to US6048730 but with different assignee.
	US6048730	Selectable marker for development of vectors and transformation systems in plants	Waldron C.	Novartis AG	19-Sep-90	11-Apr-00	Almost identical to US 5668298 but with different assignee. Subject to terminal disclaimer.
	EP0186425	A selectable marker for development of vectors and transformation systems in plants	Waldron C.	Lilly Co. Eli (US)	18-Dec-85	2-Jul-86	
6.Transformation method, Biolistic							
	US4945050	Method for transporting substances into living cells and tissues and apparatus therefor	Sanford et al	Original assignee: Cornell Research Foundation, licensed to Du Pont with exclusive rights	13-Nov-84	31-Jul-90	Biolistic apparatus (PDS-1000/He) was purchased from Bio-Rad. Biolistic technology is exclusively licensed to Bio-Rad from Du-Pont de Nemours & Co . License states that apparatus is solely for research, and not for commercial use or applications. For any commercial licensing, user must contact Du Pont. Letter acknowledging license agreement sent to Bio-Rad, accepted. Refer to App. 6&7
	US5100792	Method for transporting substance into living cells and tissues	Sanford et al	Original assignee: Cornell Research Foundation, licensed to Du Pont with exclusive rights	24-Jan-89	31-Mar-92	
	US5204253	Method and apparatus for introducing biological substances into living cells	Sanford et al	Du Pont de Nemours	29-May-90	20-Apr-93	

Continued...

Protocol/ Materials	Patent No[a]	Title	Inventor(s)	Assignee	Filing Date	Issue Date[b]	Source and/or Licensing Requirement(s)
	EP0331855	Apparatus for delivering substances into cells and tissues in a non-lethal manner.	Sanford et al	Biolistics, Inc.	30-Sep-88	13-Sep-89	
	EP535005B1	Improved method and apparatus for introducing biological substances into living cells.	Bruner et al	Du Pont de Nemours	29-Apr-91	24-Aug-94	
	WO9118991	Improved method and apparatus for introducing biological substances into living cells.	Bruner et al	Du Pont de Nemours, Cornell Research Foundations and Duke University	29-Apr-91	12-Dec-91	
	WO9220809	Method of creating a transformed rice plant	Christou et al	Agracetus INC	15-May-91	26-Nov-92	
	US6004287	Biolistic apparatus for delivering substances into cells and tissues	Loomis et al	N/A	23-Sep-98	21-Dec-99	
	WO0016828	Biolistic apparatus for delivering substances into cells and tissues	Loomis et al	N/A	23-Sep-99	30-Mar-00	
7. Plant Tissue Culture and Regeneration							
	US4666844	Process of regenerating cereals	Cheng S.K.	Sungene Technologies Corp	7 Sep 84	19-May-87	
	WO9419930A1	Enhanced regeneration system for cereals	Nehra et al.	National Research Council of Canada	10-Mar-94	15-Sep-94	
	US5350688	Method of regeneration of rice plants	Matsuno T & K. Ishizaki	Kirin Brewery (JP)	16 Jun 92	27-Sep-94	
	JP1256381A2	Induction and propagation of rice callus	Matsuno T & K. Ishizaki	Kirin Brewery Co. Ltd	31-Mar-88	12-Oct-89	

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Protocol/ Materials	Patent No[a]	Title	Inventor(s)	Assignee	Filing Date	Issue Date[b]	Source and/or Licensing Requirement(s)
8. Molecular Analysis							
PCR Analysis							
	US5656493	System for automated performance of the polymerase chain reaction	Mullis et al	The Perkin Elmer Corporation	18-Feb-94	12-Aug-97	PCR machine used was from MJ Research. A generic license might be applicable, from Roche Molecular Systems Inc, 1145 Atlantic Avenue, Alameda CA, 94501, USA Phone: 5108142970.
	EP0236069	Apparatus and method for performing automated amplification of nucleic acid sequences and assays using heating and cooling steps	Johnson et al	Cetus	25-Feb-87	9-Sep-87	
	EP0776967	Heat exchanger for use in a temperature cycling instrument	Johnson et al	The Perkin Elmer Corporation	25-Feb-87	4-June-97	
	US4683202	Process for amplifying nucleic acid sequences	Mullis	Cetus	25-Oct-85	28-Jul-87	
	US4683195	Process for amplifying, detecting and/ or cloning nucleic acid sequences	Mullis et al.	Cetus	7-Feb-86	28-Jul-87	
	US4965188	Process for amplifying, detecting and/or cloning nucleic acid sequences using a thermostable enzyme	Mullis et al.	Cetus	17-Jun-87	23-Oct-90	
	EP0509612	Process for amplifying and detecting nucleic acid sequences	Mullis et al.	Hoffman-La Roche	27-Mar-86	21-Oct-92	
	EP0502588	Process for amplifying nucleic acid sequences	Mullis	Hoffman-La Roche	27-Mar-86	9-Sep-92	
Taq polymerase	EP0502589	Kit for use in amplifying and detecting nucleic acid sequences	Mullis et al.	Hoffman-La Roche	27-Mar-86	9-Sep-92	Taq polymerase was both purchased from Promega and produced on premises
	US4889818	Purified thermostable enzyme	Gelfand et al.	Cetus	17-Jun-87	26-Dec-89	
	EP0258017	Purified thermostable enzyme and process for amplifying, detecting, and/or cloning nucleic acid sequences using said enzyme	Erlich et al.	Cetus	21-Aug-87	2-Mar-88	

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Protocol/ Materials	Patent No[a]	Title	Inventor(s)	Assignee	Filing Date	Issue Date[b]	Source and/or Licensing Requirement(s)
9. Viral coat protein mediated protection							
	EP240331	Virus resistant plants having a viral coat protein	Loesch-Fries et al.	Lubrizol Genetics, Inc.	1-Apr-87	7-Oct-87	
	WO9612028A1	Production of peptides in plants as viral coat protein fusions	Turpen et al.	Biosource Technologies, Inc.	6-Oct-95	25-Apr-96	
	US5316931	Plant viral vectors having heterologous subgenomic promoters for systemic expression of foreign genes	Donson et al.	Biosource Technologies, Corp.	31-Jul-92	31-May-94	
	US5589367	Recombinant plant viral nucleic acid	Donson et al.	Biosource Technologies, Inc.	19-Jan-94	31-Dec-96	
10. DNA Sequencing using an ABI Prism 377 sequencer (Perkin-Elmer, USA)							No agreement was signed

[a] Abbreviation of Countries: EC - European Community, JP- Japan, US - United State of America, WO - World Intellectual Property Organization

[b] In the USA, the term of utility patent depends on when patent application was filed. If the patent issued from an application filed prior to June 8, 1995, the term is the later of (1) 17 years from the date of issuance of the patent, or (2) 20 years from the first U.S. filing date for the patent. If the patent issued from an application filed on or after June 8, 1995, then the term is 20 years from the first U.S. filing date for the patent. For further information, see http:/www.patents.com/patents.sht

[c] Plant germplasm under the auspices of FAO. Joint Agreement between IRRI and FAO stated that IRRI shall hold the designated germplasm for the benefit of the international community. IRRI shall not claim legal ownership over the designated germplasm nor shall it seek any intellectual property rights over that germplasm or related information. The germplasm and related information available directly to users through FAO, for the purpose of scientific research, plant breeding or genetic resource conservation, without restriction. Furthermore, where samples and/or related information are transferred to the third party, IRRI shall ensure that the receiver bound to the conditions set above. However this provision shall not apply to the repatriation of germplasm to the country that provided such germplasm.

Table 2: Product Clearance Profile (Relevant Components and Technologies) of Hoja blanca virus resistant transgenic rice

Note that the list of possible applicable patents in this table is not a legal document and will require verification by CIAT's legal counsel

Primary Component or Technology	IP and TP on General Process, Technology or Gene Sequence		Relevant Patents	Potential/Existing Applicable License(s)	Owner of Tangible Property
Rice , *Oryza sativa* cv Cica 8			Not found	Designated FAO in trust germplasm	
RHBV N Gene	cDNA Synthesis	Reverse transcriptase	US5668005	Life Technologies	
Viral Coat Protein Mediated Protection			EP240331 WO9612028A1 US5316931 US5589367	Lubrizol Genetics Inc. Biosource Technologies Biosource Technologies Biosource Technologies	
Cloning Vector		pBS (Stratagene)	US512856 US5188957 US5286636 EP0286200 WO8805085	Stratagene Stratagene Stratagene Stratagene Stratagene	
		pRT101 PGSFR761A		None in place, No MTA None in place, No MTA	Max Planck PGS.
Selectable Marker	Promoter	CaMV 35S 5'	US4407956, US5352605 US5858742 US5550318 US5322938 WO8402913	The Regents of UC Monsanto Co. Monsanto Co. Dekalb Genetics Monsanto Co. Monsanto Co.	
	Structural Gene	*aphIV*	US5668298 US6048730 EP186425	Eli Lilly and Co. Novartis AG Eli Lilly Co. (US)	
	Terminator	Nos 3'	US5352605	Monsanto Co.	
Gene of Interest	Promoter	CaMV 35S 5'	See cell above	See cell above	
	Structural Gene	RHBV Nucleoprotein (N)	None found		CIAT
	Terminator	Nos 3'	US5352605	Monsanto Co.	
Tissue Culture and Regeneration	Culture initiation and regeneration		US4666844 WO9419930A1 US5350688 JP1256381A2	Sungene Technologies Nat'l. Res. Council Canada Kirin Brewery (JP) Kirin Brewery Co. Ltd.	

continued...

Table 2 continued

Primary Component or Technology	IP and TP on General Process, Technology or Gene Sequence		Relevant Patents	Potential/Existing Applicable License(s)	Owner of Tangible Property
Plant Transfor-mation	Broad method-specific claims	Biolistic	US4945050	Cornell Research Foundation (CRF) , DuPont	
			US5100792	CRF, DuPont	
			US5204253	DuPont	
			US5036006	CRF	
			EP0331855	Biolistics, Inc.	
			EP535005B1	DuPont	
			WO9118991	DuPont	
			WO9220809	CRF & Duke Univ.	
			US6004287	Agracetus Inc.	
			WO0016828	N/A	
				N/A	
	Mechanical apparatus used	PDS-1000/He (Bio-Rad)		Bio-Rad	
Analytical and Molecular Methods	pre- and post-transformation laboratory methods used to develop the transgenic product	PCR	US5656493	Perkin Elmer Corp.	
			EP0236069	Cetus	
			EP0776967	Perkin Elmer Corp.	
			US4683202	Cetus	
				Cetus	
			US4683195	Cetus	
			US4965188	Hoffman-La Roche	
			EP0509612	Hoffman-La Roche	
			EP0502588		
		Taq Pol	EP0502589	Hoffman-La Roche	
			US4889818	Cetus	
				Cetus	
			EP0258017		

2.1.3 *Proprietary Property Management Analysis*

Plant Seed/Source

Rice cultivar Cica 8, the Colombian commercial variety used in the transformation experiments is designated as *in trust* germplasm (Accession No. IRRI-IRGC 53078) under the IRRI-FAO agreement. The global mandate for rice genetic resources conservation is held by the International Rice Research Institute ("IRRI") while CIAT has a regional mandate for Latin America. The germplasm originated from and was donated by Colombia to the IRRI Gene Bank. Since the germplasm is FAO designated it can be used for any agricultural research and breeding purposes without any restriction. However, CIAT or any recipient of the designated germplasm has no rights to obtain IP protection on the germplasm or related information or claim ownership of the germplasm. These particular conditions have direct implications on the ownership of the materials developed through recombinant DNA technology, particularly transformation and is addressed in the discussion portion of this Audit. It should be noted that at present, it is not yet clearly established within the international community whether the transformation of a designated line affects the FAO designated status of progeny.

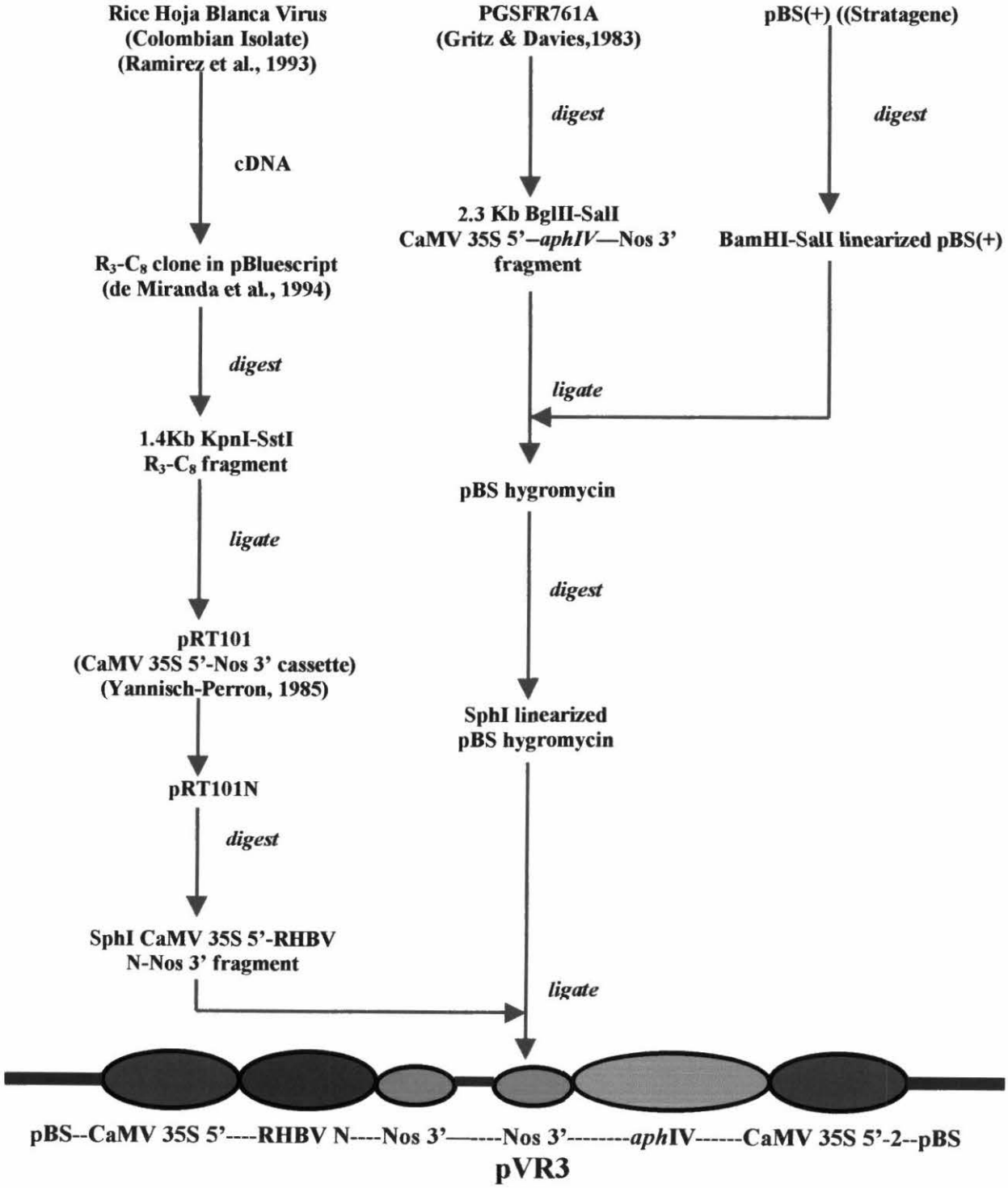
Gene Construct(s)

The plasmid pVR3 (Appendix 2) used in rice transformation was made using DNA fragments from plasmid constructs, pRT101 (Appendix 3) and PGSFR761A (Appendix 4) that are originally from Max Planck Institute, Germany and Plant Genetic Systems, Belgium, respectively (Figure 1). Both plasmids were brought to CIAT by Dr. Jorge Mayer without MTA or documentation. Dr. Mayer is a former CIAT Senior Scientist who is now with the Center for the Application of Molecular Biology to International Agriculture ("CAMBIA") in Canberra, Australia. The procedure for the construction of the pVR3 and the flow of TP related to this are illustrated in Fig.1. It should be noted that the transfer of TP to create pVR3 involved only fragments of plasmids pRT101 and PGSFR761A. pRT101 was utilized as the source of the CaMV 35S promoter and Nos terminator for the N gene which was earlier produced by CIAT researchers through cDNA synthesis. On the other hand, PGSFR761A was used as the source of the entire expression cassette of the hygromycin resistance gene (*aphIV*) driven by CaMV 35S promoter and Nos terminator. The cloning vector used to amplify these fragments in *E. coli* was pBS (+) (Appendix 5) from Stratagene, USA. The TP contained in pVR3 therefore, appear to be derived from four distinct sources: a) Max Planck Institute, Germany b) CIAT, Colombia c) Plant Genetic Systems, Belgium and d) Stratagene, USA. However, since the transfer of pRT101 and PGSFR761A are not covered by MTAs, the authorized extent of use of these plasmids from Max Planck Institute and Plant Genetic System is not established.

pVR3 has the following components which might be covered by IP.

- CaMV 35S promoter, a viral promoter active in plants that may be covered by US patents held by the Regents of University of California, Dekalb Genetics (now owned by Monsanto) also in the US and Monsanto (now owned by Pharmacia) in the US and other countries. It should be noted that this promoter was obtained from Max Planck Institute and Plant Genetic System (the latter is now owned by Aventis) and was used to drive two distinct types of genes, N and *aphIV* in two separate expression cassettes. At this point, it is not clear

Figure 1: Flow chart for the construction of pVR3 and associated transfer of tangible properties



Source: Compiled by Reynaldo Ebora while on an IP Management training internship with ISAAA.
References: Gritz and Davies, Gene, 25 (1983) 179-188. de Miranda et al. J Gen Virol 75, 2127-2132, 1994. Ramirez, et al. Journal of General Virology (1993), 74, 2463-2468. Yanisch-Perron, et al. Gene, 33 (1985) 103-119.

whether the promoters used to express these two genes are identical. From the plasmid maps of pRT101 and PGSFR761A provided by CIAT to the Auditors the promoter used to express the RHBV N gene was labeled as CaMV 35S promoter while it was CaMV 35S-2 for *aphIV*. Further details on these constructs are not yet obtained at this time. It is crucial to establish the actual composition of the promoters used in the transformation studies, whether it is CaMV 35S, tandem CaMV 35S, CaMV 35S with tandem enhancer sequence or CaMV 35S with additional regulatory sequence from other sources, since this aspect will determine what other intellectual and tangible properties are involved.

- Nos terminator which appears to be also covered by US 5352605, a patent primarily on CaMV 35S promoter issued to Monsanto. This regulatory sequence was also obtained from Max Planck Institute and Plant Genetic System and was also used as part of the regulatory sequence of N and *aphIV* genes.
- N gene - The cDNA of RHBV N gene was synthesized using the Superscript II reverse transcriptase purchased from Life Technologies, Inc., USA who holds the patent for the said enzyme.
- *aphIV* - covered by two identical US patents, assigned to Eli Lilly and Co. and Novartis, and another European patent under Eli Lilly (US). There presumably exists common ownership of the invention by the two assignees of the two US patents, since US6048730 (Novartis) posts notice that "This patent is subject to a terminal disclaimer." For additional reference on this general subject, please refer to http://www.bitlaw.com/source/mpep/706_02.html
- pBS (+) cloning vector - covered by three US, a European and an International patents owned by Stratagene. Authorized use of this plasmid vector is for research purposes only. Conditions are stipulated in the "Notice to Purchasers" which accompanies product (see Appendix 5).

Transformation

CIAT used a Biolistic® PDS-1000/He System from Bio-Rad Laboratories Inc. for the particle bombardment of rice calli. CIAT researchers did not sign the standard purchase agreement (Appendix 6) from the company, but Dr. William M. Roca, Head of the Biotechnology Research Unit sent a letter (Appendix 7) to Bio-Rad indicating that the equipment will be used for research purposes only, specifically for the genetic transformation of cassava, rice and phaseolus beans. The Auditors interpret this to be in lieu of, but in general compliance with the standard licensing agreement. In the Bio-Rad purchase agreement, the phrase "use for commercial purposes" is defined to include the production, use or transfer for consideration of apparatus, process, or product for performing the biolistic process. The use of the Bio-Rad PDS-1000/He System brings the purchaser a research only license. This technology is exclusively licensed by DuPont to Bio-Rad, and for any commercial licensing, the user must contact DuPont. The biolistic apparatus and transformation process for rice may fall under a cascade of US, European and worldwide patents. However, the list of member states to the Patent Cooperation Treaty (PCT) updated on September 20, 2000 does not include Colombia, where the rice biolistic transformations were performed. As a consequence, the patents to the biolistic processes and equipment components may or may not be enforceable in Colombia due to the territoriality of patents.

The PCT was concluded in 1970, amended in 1979 and modified in 1984. This treaty makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an "international" patent application which can be filed by anyone who is a national or resident of a contracting State. However, among the 8 countries that are identified as potential users of the technology by Dr. Lee Calvert (personal communication, 2000) only Costa Rica is a member of the PCT since August 3, 1999. Colombia, Venezuela, Ecuador, Peru, Panama, Haiti and the Dominican Republic are not party to the treaty. This means that the three international patents (WO/9118991, WO/9220809, WO/0016828) will not apply to these countries, because patents are country specific. Furthermore, patent claims may be granted for different kinds of invention, claims may be worded to cover products *per se*, products-by-process (or method), uses, or processes (or methods). Whereas the first three types of claims generally extend to the products that embed the new discoveries, "process or methods" claims or claims for the claimed technical methods or procedures do not necessarily extend to the products that are produced by the claimed processes or methods. What is of great importance for "process" claims is the country in which the process is applied. If the product is made in a country where those "process" claims have not been issued, then a license for such claimed processes is likely not required.

The transformation system developed by CIAT using immature panicle might involve innovative steps that are not yet fully covered by any patents. It might be worthwhile for CIAT to explore the patentability of this technique while it is being further developed.

Recommendation 1:	**CIAT may wish to explore the patentability of CIAT's developed transformation system using immature panicles as this technique is being further developed.**
This is partly also a matter of policy as to whether or not CIAT wishes to engage in the patentability of its own inventions.	

Transformed Cell/Embryo Selection

The use of hygromycin for selection of transformed cell appears to be covered by two US patents assigned to Eli Lilly and Co and Novartis AG and one European patent assigned to Eli Lilly.

Plant Regeneration System

The techniques CIAT used to regenerate plants may partially overlap with the claims of US patents assigned to Sungene Technologies Corp (US) and Kirin Brewery (JP), Japan patent assigned to Kirin Brewery Co. Ltd. and an international patent assigned to National Research Council of Canada.

Screening /Molecular Analyses

Screening processes used to determine transformation cover a wide range of laboratory tools, chemicals, processes and applications. Such screening requires the use of, but may not be limited to, monoclonal antibodies, probes, primers, and PCR and its requisite *Taq* polymerase. With the purchase of most of these components through normal commercial channels, from licensed suppliers, the purchaser is typically granted a license legitimizing use of that component for any research or commercial purpose. When, in the interest of cost savings or for any other reason, unlicensed supply sources provide such laboratory materials, the research project is in danger of

violating certain IP rights. At least some laboratory supplies for the CIAT RHBV Resistant Transgenic Rice Project, appear to have been obtained from both licensed and unlicensed sources. Use of the unlicensed materials may pose certain limitations on CIAT's eventual, legitimate distribution of RHBV resistant transgenic rice products.

Discussion with the researchers showed that *Taq* polymerase was either purchased directly from Promega (Madison WI) or produced in the CIAT laboratory. CIAT researchers believe that production of Taq polymerase for local use (within CIAT) is legal in Colombia. This assumption is apparently currently true because Colombia is not a member of the Patent Cooperation Treaty (PCT) and not listed as designated state nor covered by the international patent issued by the World Intellectual Property Organization (WIPO).

The CIAT researchers used a PCR machine made by MJ Research Inc. The PCR process is covered by patents owned by Hoffmann-La Roche, Inc. and F. Hoffmann-La Roche Ltd. (collectively called Roche). It appears that licenses are required both for the use of thermal cycler and the enzyme *Taq* polymerase.

Viral Coat Protein Mediated Cross Protection

The technique is covered by two US patents assigned to Biosource Technologies, Inc., a European patent assigned to Pioneer Hi-Breed International, Inc. and an international patent also assigned to Biosource Technologies, Inc. Negotiation for license for the use of the technology may be necessary.

2.1.4 Discussion and Conclusions

Summary of the deconstruction

The deconstruction process is an in-depth analysis of a product. Timing the deconstruction process for any particular "soon to be released product" is a management decision. This management decision will depend on the length of the product development pipeline and resources available. Adequate time should be provided to permit product developers an opportunity to re-design their product development approaches, should appropriate FTO not be obtained. Most, if not all, ag-biotechnology companies would produce a cursory product deconstruction at the R&D planning stage even prior to initiating research.

The Product Clearance Spreadsheet (Table 1 under Section 2.1.2 above) compiled the information obtained through the deconstruction process. It is typically a para-legal document, prepared by someone close to the product development process, to assist the organization's patent counsel. The FTO must be produced by a patent attorney. It will advise the organization regarding how to proceed with the product development and release process.

The preparation of this spreadsheet was a tedious process since all the necessary information was scattered between many different departments, files, people, and documents. It should be noted that systematic recording of all relevant information is critical because once certain key staff leaves CIAT, there is a significant loss of institutional memory which would make it almost impossible to conduct a deconstruction of a certain product. For such a systematic recording, a robust laboratory notebook procedure may prove helpful.

Recommendation 2: CIAT should institute a laboratory notebook protocol

To reduce the resources necessary to produce a Product Clearance Spreadsheet, FTO, and Product Clearance Profile, CIAT should urgently set in place protocols for universal laboratory notebook use and archiving.

Note that the Auditors drafted a proposed laboratory notebook policy and working guidelines for CIAT's consideration; this is given in Section 2.4 below.

Recommendation 3: Setting-up of a Database and related management practices concerning the release of germplasm

Also, CIAT may want to consider instituting adequate database and related management practices to assure that the release of all germplasm, regardless of the recipient (CIAT or non-CIAT), is accompanied by an appropriate MTA. Details of all such MTAs must be properly archived, searchable, and readily reportable.

The Product Clearance Profile (Table 2 also under Section 2.1.2 above) is a brief (often one page) summary of the Product Clearance Spreadsheet. It shows the organization which components have FTO (through licensing or in other ways) and which do not.

The Product Clearance Spreadsheet, FTO, and Product Clearance Profile ought to be regularly (at least annually) reviewed and updated. All three are confidential and should be shared only on a need-to-know basis. Depending on the laws of the country(ies) involved, if properly managed, a FTO may fall under attorney-client privilege and thereby be protected from the discovery process, if lawsuits subsequently occur.

A summary of the possible licenses required is given in Table 3 below (which is a summary of Tables 1 and 2). The table demonstrates that if CIAT were to seek licenses or clearances for all the components covered by patents it might need to contact at least 24 organizations. However, an important distinction is necessary here, namely between Patent Cooperation Treaty (PCT) member countries and non-members. Many of these patents apply only to PCT member countries. The patents found in the reviewed product will likely not apply to the countries identified as potential users of RHBV resistant transgenic rice technology at this time, because, with the exception of Costa Rica, they are not (yet) PCT members.

Until recently, individuals and firms from the industrialized world typically did not incur the expenses of filing for patents in developing countries. In more recent years however, many developing countries have signed the World Trade Organization/Trade Related Aspects of Intellectual Property (WTO/TRIPs) agreements which has led to a new burst on filing for patents in WTO member countries. All countries that are identified as potential users of the RHBV resistant transgenic rice technology are members of WTO, namely:

Table 3: Possible Required Licenses and/or Agreements for Hoja blanca virus resistant transgenic rice

Sample Table
The table below should be completed by CIAT's legal counsel from data from Table 1 which has been updated/verified by legal counsel

Organization	Possible Relevant Patents	License and/or Agreement
Agracetus Inc.	WO9220809, US6004287, WO0016828	
Biolistics, Inc.	EP0331855	
Bio-Rad		PDS-1000/He
Biosource Technologies	WO9612028A1, US5316931, US5589367	
Cetus	EP0236069, US4683195, US4965188, EP0258017	
Cetus thereafter Hoffman-La Roche	US4683202, US4889818	
Cornell Research Foundation	US5036006	
Cornell Research Foundation, DuPont	US4945050, US5100792	
Cornell Research Foundation, DuPont & Duke Univ.	WO9118991	
Dekalb Genetics	US5550318	
DuPont	US5204253, EP535005B1	
Eli Lilly and Co.	US5668298, EP186425	
Hoffman-La Roche	EP0509612, EP0502588, EP0502589	
Kirin Brewery (JP)	US5350688, JP1256381	
Life Technologies	US5668005	
Max Planck Institute, Germany		pRT101, No MTA
Monsanto Co.	US5352605, US5858742, US5322938 WO8402913, US5352605, US5352605	
National Research Council of Canada	WO9419930A1	
Novartis AG	US6048730	
Perkin Elmer Corp.	US5656493, EP0776967	
Lubrizol Genetics Inc.	EP240331	
Plant Genetic System, Belgium		PGSFR761A, No MTA
Regents of Univ. of California	US4407956	
Stratagene	US512856, US5188957, US5286636 EP0286200, WO8805085	
Sungene Technologies	US4666844	

Note that although a company may own another company (e.g. DuPont having purchased Pioneer Hi-Bred International Inc.), certain patents may still be owned and/or rights assigned to Pioneer in which case certain licenses may have to be sought from Pioneer. Determining the current ownership is a relatively tedious process and is always evolving as companies re-structure, sell patents or provide exclusive licenses with the right to sub-license.

- Costa Rica – 1 January 1995
- Peru – 1 January 1995
- Venezuela – 1 January 1995
- Dominican Republic - 9 March 1995
- Colombia - 30 April 1995
- Ecuador – 21 January 1996
- Haiti – 30 January 1996
- Panama – 6 September 1997

TRIPs agreements require the signatories to established and maintain a prescribed level of IP rights protection. Thus, with the rise of a more global economy, technologically advanced products such as RHBV resistant transgenic rice may be produced, distributed and consumed on a worldwide basis. Therefore, the effects of IP and TP rights must be considered on a more global scale than was previously necessary. Furthermore, CIAT, although operating in Colombia where no relevant patents have been issued, is not free of the TP rights issues that are involved (see also the next sub-section on the distinction between IP and TP rights).

Recommendation 4: Product Clearance Spreadsheet and FTO Information

CIAT should establish internal capacity to prepare the required documentation for FTO Reviews.

Specific to the RHBV Resistant Transgenic Rice Project, CIAT management will need to consider the risks and rewards of the following strategic options:

A. do not obtain any further agreements for the components specified in the Product Clearance Spreadsheet

B. obtain commercial licenses/agreements for each of the components

C. obtain commercial licenses/agreements for selected components only

D. reconstruct the entire RHBV resistant transgenic rice product using components for which no commercial license/agreement is required

Recommendation 5: Agreement management procedures

CIAT ought to consider a process for adequate recording, archiving and managing of its agreements with non-CIAT entities. This will require on-going consultation between a designated CIAT agreement negotiator and CIAT management. Further, it will require the establishment and maintenance of a database that will delineate CIAT's rights and obligations *vis-à-vis* non-CIAT entities under its agreements.

The Critical Distinction between IP and TP (see also Kryder, Kowalski and Krattiger, 2000)
Since the transfer of TP is so closely associated with the transfer of IP it is important to define and identify the distinctions between the two. Scientists have traditionally exchanged materials among themselves for research purposes and this system has served the scientific community

well. Such exchanges are often formalized through MTAs that stipulate the conditions by which materials are provided to a third party (including matters on confidentiality, under what conditions, if any, the material maybe transferred to another party, what happens if an invention takes place based on work with the material, etc.). What is often ignored is that such transferred material (which is the subject of TP) may contain the IP of others and that MTAs typically do not provide the recipient with rights to use such IP. Similarly, even if the right for using IP embedded in the transferred material has been granted through licenses, such licenses do not *a priori* provide authorization to distribute the TP which was originally transferred.

Suppose Researcher A constructs a vector with the following components:

a) a synthetic gene constructed in his/her laboratory; and files a patent application
b) the CaMV 35S promoter (owned by Monsanto and obtained under a MTA from Monsanto for research purposes only)
c) a plasmid which is in the public domain

Researcher A now transfers the construct to another researcher, Researcher B, under a MTA for research purposes only. If Researcher B then wishes to use a product containing the construct, the following agreements may be necessary:

- A license from Researcher A for use of the synthetic gene (TP) and any related patents that may have been granted (IP) as specified in "a" above.
- A license from Monsanto for use of the 35S promoter, as specified in "b" above.
- A license from Researcher A for use of the plasmid (TP). Note that despite the fact that the plasmid is in the public domain, Researcher Y obtained it under an MTA and therefore may require a license to use that TP.

More generically, CIAT has six options on how to proceed; these have been discussed more extensively in Kryder, Kowalski and Krattiger (2000). See Table 4 for a summary of these options.

As a consequence, resolving the IP and TP issues becomes often much more complex than originally envisaged, particularly if MTAs are involved. These MTAs are often prepared without consideration for what happens when research leads to new discoveries or to a developed product. MTAs are straightforward and provide an easy way to access TP and advance research. Yet that easy route often complicates life further down the road.

It should not be concluded that MTAs should therefore be avoided, quite on the contrary, but the practical implications of MTAs are often misunderstood.

Table 4: Alternative and/or Complementary IP/TP Management Options to Obtaining Freedom-to-Operate for "Any CIAT Biotechnology Product"

Title	Emphasis	Description
1. Invent around current patents	Science and research based approach	Research alternative ways to develop "any CIAT biotechnology product", generating new inventions
2. Re-design constructs	Product development based approach	Re-design each construct to reduce number of applicable patents, whenever possible synthesize own genes to reduce reliance on TP of others
3. IP/TP Owners to Relinquish Claims	Humanitarian approach focused on public perception	All FTO issues for all "any CIAT biotechnology product" related activities, commercial or otherwise, are eliminated through public (or private) statements and related activities by the certified owners/assignees of each set of IP/TP rights for making, having made, using, having used, importing, exporting, selling, and having sold all "any CIAT biotechnology product" plants, plant parts, and all related products and processes.
4. Ignore all IP and TP	Short term perspective	All FTO issues for all "any CIAT biotechnology product" related activities, commercial or otherwise, are ignored, and research and product development as well as plans for general distribution proceed.
5. Seek Licenses for all IP and TP	Licensing approach	All FTO issues are resolved by the process of any party (individually or through consortia) acquiring an appropriate (commercial or other) license from the certified owners/assignees for each set of IP/TP rights for the "any CIAT biotechnology product" related activities that are of interest to the licensee. This license may be commercial in nature (a grant to make, have made, use, have used, import, export, sell, or have sold all "any CIAT biotechnology product" plants and plant parts and all related products and processes) or a more restrictive one as the licensee and licensor mutually determine to be required.
6. Mix of all Options (1 to 5)	Pragmatic, realistic	While research and development plans are made to optimize the product, re-design of constructs and acquisition on TP is planned to minimize IP and TP conflicts (OPTION 2); selected FTO issues are removed through public (or private) rescinding of rights by selected holders of certain IP/TP rights (OPTION 3); this "moral high ground" is used to leverage additional rights holders to either rescind their claims (OPTION 3) or to reduce their demands within the context of license negotiations (OPTION 5). In the end all remaining unrescinded IP/TP rights can be either licensed (OPTION 5) or ignored (OPTION 4).

Source: Adapted from Kryder, Kowalski and Krattiger (2000). The Intellectual and Technical Property Components of pro-Vitamin A Rice (*Golden*Rice™): A Preliminary Freedom-To-Operate Review. *ISAAA Briefs* No. 20. ISAAA: Ithaca, NY. 56 p.

Recommendation 6: CIAT should clearly define its needs when negotiating and entering into MTAs with non-CIAT parties

MTAs are often prepared without consideration for what happens when research leads to a developed product. Because MTAs are straightforward and provide an easy way to access TP and advance research, they are often unwisely used (by many institutions) which complicates things further down the product development road. It is therefore important that CIAT understands the implications of current and future MTAs as relatively minor changes in its agreements can significantly simplify research and product distribution later on.

Recommendation 7: Consider the establishment of an Office of General Counsel

Lastly, CIAT may wish to consider instituting an Office of General Counsel to oversee and harmonize all aspects of CIAT's legal rights and obligations among its staff members and categories of service.

CIAT's Standard Material Transfer Agreement

CIAT is already addressing the IP rights issues related to recent developments like TRIPS and the Convention on Biological Diversity (CBD) by establishing the CIAT's Policy on IP Rights (Appendix 8). The revised version of this policy was approved by the CIAT Board of Trustee in December 1998. The implementation of the said policy is defined in the following sets of protocols:

- Protocol I: For Plant Genetic Resources
  - A: Plant genetic resources placed under the auspices of the FAO, otherwise known as the designated collection.
  - B: Material obtained after the United Nations Convention on Biological Diversity came into force in December 1993.
- Protocol II: For Breeding Lines, Elite Germplasm and Hybrid Materials
- Protocol III: For Materials Derived from Genetic Engineering
- Protocol IV: For Microorganisms and Biological Control Agents
- Protocol V: For Publications, Databases, Software and Equipment
- Protocol VI: For Research Products Developed by CIAT Staff

CIAT also has a standard MTA (Appendix 9) form that covers most of the IP and TP concerns based on its IPR Policy. The Auditors noted the following points in the MTA that merit further analysis and discussion.

Designated Germplasm

"The material is held in trust under the terms of an agreement between CIAT and FAO, and the recipient has no rights to obtain Intellectual Property Rights (IPR) on the germplasm or related information" (emphasis added)

Preamble

"This MTA is written to conform fully with the provisions of the United Nations Convention on Biological Diversity, and the terms and conditions of the Agreement signed on 26 October 1994 between CIAT and the Food and Agriculture Organization of the United Nations (hereafter referred to as FAO), for the conservation of the germplasm collections kept in trust by CIAT (and named designated) under the auspices of FAO."

The term "related information" needs to be defined. Examination of the documents (CIAT's Policy on IP Rights and Material Transfer Agreement) revealed that this term was used in several occasions but was not defined. Apparently, it is assumed that the term has common definition and interpreted in the same way by all, which, in practice, does not seem to be the case. It is crucial that examples of "related information" be given and its actual scope be identified because it will have implications as to what materials or information derived from the germplasm, microbial isolates or biological control agent can be patented. For instance, can a primer whose sequence was derived from the plant genome of a FAO designated plant be protected? Do genetic map or gene sequences from a FAO designated germplasm fall under this protection? Does "related information" refers to all the biological information present in the FAO designated germplasm? If these things are covered by "related information", then it could not be protected as indicated in the general provision of the MTA. On the other hand, under Protocol III: For Materials Derived from Genetic Engineering, these biological information are classified as part of the intermediate or final products and of derived and associated materials. This is a possible source of confusion later because the other contracting party who is signing the MTA will be relying only on the provisions indicated in that particular document. The term "related information" might be clear on the side of CIAT because it is defined in the CIAT's IPR Policy and Protocols, but can be a gray area for the other party because these documents are not integral parts of the MTA.

It must be clearly stated, however, that an attempt by CIAT to define the term "related information" in its current or near-term agreements is not recommended here. This is a politically charged issue currently being addressed by the CGIAR System (e.g. International Centers Week 2000) and under the negotiations leading to the revisions of the FAO International Undertaking. CIAT must be extremely cautious in this area.

Once the term has been defined by the international community, then the situation could be addressed by any of the following approaches:

A. Include the definition of the term "related information" and identify its scope in the MTA.

B. Attach the CIAT's IPR Policy and Protocols in the MTA as appendices.

C. Clearly identify in the body of the MTA what "related information" could or could not be protected.

Terms and Conditions of MTA

> *"Article 1. This Material Transfer Agreement is between the two institutions through their legal representatives."*

With respect to the RHBV Resistant Transgenic Rice Project it would be advisable to negotiate with Max Planck Institute and Plant Genetic System regarding plasmid constructs pRT101 and PGSFR761A which were used as sources of the regulatory sequences (CaMV 35S promoter and Nos terminator) and *aphIV* gene to create pVR3, which was used in the actual rice transformation. Because the plasmids were used without any MTA and transgenic plants are already produced, the agreement should include conditions on the use of the transformed plants instead of the use of the plasmid. The transfer of tangible properties (DNA sequences integrated into the plant genome) could be determined using the available molecular data. The MTA should be between institutions through their legal representatives and should be prepared with the help of the researchers so that the specific technical issues to be addressed could be properly incorporated in the document.

> *"Article 3. CIAT is distributing the germplasm described herein for purposes such as conservation, research, plant breeding or training, without any restriction." (emphasis added)*

The term "without any restriction" is contradictory to Article 4 (discussed below) and is not accurate since the release of the material is covered by a MTA which specifically defines the conditions that should be complied with for use of the material. This could be revised to "CIAT is distributing the germplasm for purposes such as conservation, research, plant breeding or training in accordance to the terms and conditions indicated in this MTA".

> *"Article 4.The Recipient shall not claim legal ownership over the material received nor seek intellectual property protection over that material and related information. The Recipient shall not transfer the original material referred to in this MTA or any copy of it to a third party without ensuring that the party is bound by the obligations of a Recipient under this MTA. The obligations of the Recipient mentioned in this MTA extend to the substantially equivalent reproductive or vegetative progeny of the material." (emphasis added)*

It would help if the terms "related information" and "substantially equivalent reproductive or vegetative progeny of the material" are defined. As indicated before, the term "related information" could be interpreted as any biological information derived from the plants like DNA or RNA sequences, protein sequences, genetic maps, etc. but has not been defined by the international community. As a consequence, once again, CIAT must tread very carefully in this area.

The term and concept "substantially equivalent reproductive or vegetative progeny of the material" should also, in an ideal world, be clearly defined especially for those materials that are products of genetic engineering. But once again, this area is currently being debated in different international fora and CIAT should await the outcome before inclusion of definitions of its own.

It could be argued that transgenics are substantially equivalent to the untransformed germplasm because a transgenic carries 100% of the original genetic material. In fact, the concept of substantial equivalence is presently being used in the regulation of genetically modified food, including under *Codex Alimentarius* (under the auspices of FAO and the World Health Organization [WHO]), an approach that is strongly opposed by the anti GMO movement. Thus, one could argue that should the transgenic be classified as substantially equivalent to the original material obtained from CIAT then its original FAO designated status is retained and thus it cannot be patented. This is not in agreement with the CIAT's protocol for materials derived from genetic engineering.

The critical matter of specific definitions is an area that CIAT must exert caution. Some specific technical and legal terms are "terms of art", and have both technical and legal meaning (e.g. essentially derived variety, parental material, substantial equivalence, intermediary biotechnology products). In our opinion, it is not in the best interests of CIAT at this time to engage in a more detailed analysis and definition of these terms, as these discussions are currently underway in a number of other fora, including within the CGIAR system (genetic resources policy committee) and the FAO (International Undertaking on a multilateral system for genetic resources). It is in our opinion preferable for CIAT to allow others to define these terms and the implications thereof, and then decide whether that is the definition it chooses to follow.

> *Article 5. The Recipient may claim intellectual property protection on the products of breeding activities through plant variety protection that is consistent with the provisions of UPOV (Union Internationale pour la Protection des Obtentions Vegetales) Convention of 1991, and that does not preclude others from using the original materials for their own breeding activities.*

The above-mentioned MTA article should also categorically classify the FAO designated transformed germplasm in order to clearly interpret the CIAT's IP Policy as defined in their Protocols presented in Appendix 8. For instance, **Protocol I: For Plant Genetic Resources**, indicated that for germplasm placed under the auspices of the FAO, otherwise known as the designated collection, CIAT will not protect the plant genetic resources by any form of intellectual property protection if it is held in trust. It further states that the recipient will not claim ownership over the material and related information. However, in **Protocol III: For Materials Derived from Genetic Engineering**, it was indicated that to ensure availability to developing nations of advanced biological technologies and/or intermediate or final products, and of derived and associated materials, CIAT may apply for intellectual property protection of the technologies or materials or may provide them to a collaborator on a restricted basis. Such arrangements will be made only when they best serve CIAT's partners. The "intermediate biotechnology products" is defined to include DNA probes, vector strains, gene constructs, primers, etc. while "final biotechnology products" include such products as transgenic organisms, genetic maps, etc. This contradiction seems to emanate from the dilemma of how to consider the transformed plant, either as "progeny" or as the original germplasm but with additional genetic character. If the transgenic plant will be considered as a progeny then it is like a product of a breeding process, and thus it can be classified as a non-designated germplasm and can be covered by plant variety protection. The provisions of Protocols I and III, therefore, are in harmony. On the other hand, if it will be considered as essentially the same germplasm (contains 100% of the genetic characteristics of the original material) but with only additional well defined

genetic character, then it should be FAO designated and cannot be protected, and thus there are certain contradictions in Protocols I and III.

Based on the opinion of Dr. Daniel Debouck (personal communication, 2000) of CIAT,

> "Transgenesis is another way to introduce a gene from an alien species into the desired crop material. The vehicle to introduce the transgene is different as compared to conventional breeding, and could use cell/protoplast/particle bombardment, *Agrobacterium*, etc. From a FAO designation perspective, I don't see the difference with an improved line produced by conventional breeding. In doing so, the Center with possible associates losses some rights, because the improved line is accessible to all and cannot be protected by IPR. Designation might be a strategy to maintain improved materials in the public domain, although I see the enforceability as a weak area for the time being and as a critical matter for this kind of materials. Thus, given trends in IPR, distribution of improved materials might be better handled through MTAs specially written for such materials."

This opinion appears to be consistent with the CIAT protocols which basically considers the transformed plants as equivalent to a product of cross breeding and thus should not be FAO designated and eligible for plant variety protection.

However, classifying the transgenics as similar to the progenies produced through conventional breeding and therefore to be protected under UPOV, might encourage the issuance of exclusive rights to transgenic accessions which are nearly identical to their FAO designated sources. Genetic transformation might therefore be used by some groups to circumvent FAO designation and stipulation that it should be made available to all for conservation, agricultural research and breeding purposes.

As part of the CIAT IP Policy on the research products developed by CIAT Staff, it was clearly indicated in Protocol VI that any idea, invention, process or other form of actual or potential IP (whether able to be protected by property rights or not) that a staff member invents during his or her employment at CIAT must be disclosed, and shall belong, to CIAT. However, there is no clear policy on the research undertaken by CIAT staff in other institutions. For instance, how to handle the product of research conducted by CIAT staff while undertaking graduate studies abroad? Concerning the germplasm brought and used by CIAT's staff to foreign institutions for their own research, should MTAs be enough or should such exchanges also be covered by additional research agreements?

It appears that the policy regarding the status of transformed germplasm and the materials developed through collaborative research need further clarification. It is recommended that CIAT should recognize this and implement a policy that comprehensively addresses these issues.

Recommendation 8: Review and revise CIAT's standard MTA

CIAT should review CIAT's standard MTA for inconsistencies within the MTA and between the MTA and other stated policies.

2.2 *Brachiaria*

2.2.1 *Introduction*

Brachiaria grasses are the most widely grown and among the most economically important forages grown throughout tropical America. CIAT has targeted three major agroecological zones for development of *Brachiaria*: savannas, forest margins and hillsides. The mission of CIAT's Tropical Forages Program (TFP) is to contribute to the welfare of small farmers by increasing livestock production, while preserving and building the natural resource base. In Brazil alone the hectares of *Brachiaria* pastureland are estimated to be between 30 and 70 million, which is significant when one considers that the introduction of *Brachiaria* was initiated only 25 years ago.

Recognizing this rapid deployment, utilization and increasing importance of *Brachiaria*, CIAT has established a breeding program, within the TFP, directed towards the development of advanced cultivars with improved characteristics, for example aluminum tolerance, insect (spittlebug) resistance and edaphic adaptation. The overall goal of this breeding program is to overcome some of the limitations found in the currently grown *Brachiaria* cultivars, which are widely recognized as having serious defects, e.g., susceptibility to spittlebug and failure of sward regeneration because of poor seed viability.

Whereas CIAT holds one of the world's largest collections of *Brachiaria* germplasm, until recently exploitation of the genetic potential of this resource was limited to the evaluation and utilization of targeted accessions. This was largely because the tetraploid species *B. decumbens* and *B. brizantha* are both apomicts that reproduce principally via facultative apospory. Apomixis is a "double-edged" sword in the improvement of *Brachiaria*. Although it presents a considerable obstacle for sexual crossing and genetic recombination, if crosses can be made, and breeding progresses, favorable genotypes can be "fixed" via the apomictic mode of reproduction and thereafter propagated indefinitely through seed. The TFP at CIAT has been able to precisely manipulate this situation to institute a successful breeding program for the development of advanced cultivars of *Brachiaria*. *B. decumbens* and *B. brizantha* are cross compatible with the induced tetraploid *B. ruziziensis*. The mode of inheritance for apomixis is likely monogenic, with apospory (simplex, *Aaaa*) dominant to sexuality (nulliplex, *aaaa*).

The TFP has therefore mobilized its scientific expertise and the germplasm resources in CIAT's collection for the purposes of breeding *Brachiaria*. As is discussed in this section of the Audit, these advances, albeit of scientific and agronomic significance, pose new and challenging questions regarding IP. The situation has changed in this regard; previously the distribution of *Brachiaria* was via accessions, and the IP landscape was mostly confined to questions surrounding FAO-designation status. However, with the prospect of advanced cultivar development, the IP situation has become more complex.

This section of the Audit addresses potential IP issues relating to this effort. Topics covered include:

- Germplasm which has been used in the breeding program.
- Varieties developed in the breeding program.

- Issues relating to FAO designation.
- Issues relating to the CBD.
- Registration of germplasm at CIAT's Genetic Resources Unit ("GRU").
- Coordination of efforts and activities between different units and programs at CIAT.

2.2.2 Germplasm which has been used in the breeding program

A total of eleven accessions of *Brachiaria* spp. went into the breeding program. Table 5 summarizes the passport data for these specific CIAT accessions. These data were provided to the Auditors by Dr. John Miles. An e-mail communication of June 29, 2000 expands on some of this information, as well as comments on the somewhat meandering route which *B. ruziziensis* (CIATFOR-26871) took on its journey from Belgium to the CIAT collection:

> "CIAT 00606 is the commercial *B. decumbens* cv. Basilisk. Two of the accessions (*B. brizantha* CIAT 6297 and CIAT 6780) are the Brazilian commercial cv. Marandu. The others, all *B. brizantha,* are "routine" germplasm accessions. The other germplasm involved in the sexual breeding population is the tetraploidized, sexual *B. ruziziensis*. We received this germplasm "informally" from Dr. Cacilda do Valle (EMBRAPA/CNPGC). I do not know the detailed history of this *B. ruziziensis* tetraploid germplasm between when its creation in Belgium (at the Catholic University of Lovain) was documented (Swenne, A., B.-P. Louant, and M. Dujardin. 1981. Induction par la colchicine de formes autotétraploides chez *Brachiaria ruziziensis* Germain et Evrard (Graminées). Agron. Trop. 36: 134-141.) and when we received it in about April 1988. Cacilda received it while she was a Ph.D. student at U. of Illinois, I believe from Stanley Shank, who was a forage grass breeder at Gainesville, FL. Shank may have received it directly from Michel Dujardin, who spent several years in Tifton, GA, or it may have taken a more circuitous route from Belgium to Florida."

After reading the Partial Draft of the Audit, John Miles sent the following e-mail (October 10, 2000), to further elaborate on, clarify and amend his previous observations on the route of the tetraploidized *B. ruziziensis*:

> "I have just seen a "Partial Draft Report" (dated 09OCT00) of the ISAAA "CIAT Proprietary Property Audit". In Section 2.2.2 you quote me on the route that the tetraploidized *B. ruziziensis* took between Belgium and CIAT. Since I wrote that (on 29JUN00), I have been informed, directly by Cacilda (in an e-mail of 25 August) in response to a direct inquiry from me, that she received this material as seed directly from Michel Dujardin. This was at an ASA (American Society of Agronomy) meeting sometime in the mid-1980's, while she was a PhD student at U. of Illinois. She grew plants from this seed at U. of Illinois and harvested (open-pollinated) seed from these. What Cacilda brought here to CIAT, in 1988, from Brazil, was vegetative material from plants grown in Brazil from her Illinois-harvested seed and also remnant seed from Illinois. I am almost certain that Stanley Shank had this material also, but apparently he was not the source of the seed sample that Cacilda received. So the path was not quite so "circuitous" as I thought in June. As far as I am aware, there is no "paper trail" to

Table 5: Brachiaria Passport Information (accession Details)

ID	CIATFOR-16829	CIATFOR-16827	CIATFOR-16296
Alternate Accession ID	BRA-004227	BRA-004219	ILCA-11043; BRA-003263
Genus	*Brachiaria*	*Brachiaria*	*Brachiaria*
Species	*brizantha*	*brizantha*	*brizantha*
Country Source	Zimbabwe	Zimbabwe	Ethiopia
Donor Country	Not Applicable	Not Applicable	Not Applicable
FAO in trust	Yes	Yes	Yes
Date of Collection	2/27/1985	2/27/1985	11/20/1984
Center Receipt Date	9/30/1985	9/30/1985	12/31/1984

ID	CIATFOR-16152	CIATFOR-16126	CIATFOR-16107
Alternate Accession ID	ILCA-13469; BRA-003026	ILCA-13373; BRA-002852	ILCA-13344; BRA-002691
Genus	*Brachiaria*	*Brachiaria*	*Brachiaria*
Species	*brizantha*	*brizantha*	*brizantha*
Country Source	Ethiopia	Ethiopia	Ethiopia
Donor Country	Not Applicable	Not Applicable	Not Applicable
FAO in trust	Yes	Yes	No
Date of Collection	10/30/1984	10/12/1984	10/10/1984
Center Receipt Date	12/31/1984	12/31/1984	12/31/1984

ID	CIATFOR-6387	CIATFOR-6780	CIATFOR-6297
Alternate Accession ID	K-75232A-E; BRA-002453, FAO-06013; FAO-06017	CPAC-3132; CNPGC-0142/80, CPI-118938; ILCA-16550	G-27/28
Genus	*Brachiaria*	*Brachiaria*	*Brachiaria*
Species	*brizantha*	*brizantha*	*brizantha*
Country Source	Kenya	Unknown	Unknown
Donor Country	Kenya	Brazil	Brazil
FAO in trust	Yes	No	Yes
Date of Collection	No data	No data	No data
Center Receipt Date	9/30/1981	10/31/1983	1/31/1980

ID	CIATFOR-606	CIATFOR-26871
Alternate Accession ID	CPI-001694; CPI-006798; BRA-001058; ILCA-10871	
Genus	*Brachiaria*	*Brachiaria*
Species	*decumbens*	*ruziziensis*
Country Source	Uganda	Unknown
Donor Country	Australia	Not Applicable
FAO in trust	Yes	No
Date of Collection	No data	11/26/1990
Center Receipt Date	1/1/1973	8/31/1990

Sources: http://oldsinger.cgiar.org and http://singer.cgiar.org

> document the movement of this germplasm from Belgium to Illinois to Brazil to CIAT. (It might be interesting to see if this material was ever entered in the EMBRAPA/CENARGEN germplasm registry.) Nor, as far as I am aware, is there any documentation of the source of the original diploid *B. ruziziensis* used in Belgium to create the tetraploid. The original publication (Swenne, Louant, & Dujardin 1981) is not specific as to it's identity or origin."

During this phase of the Audit, it was noted that individual accessions have multiple cultivar names. For example, CIATFOR-606 is variously called "Pasto Amargo, Pasto Peludo, Brachiaria, Chontalpo, and Senal." In further communications with John Miles (July 1, 2000), Auditors learned that:

> "There is a 'tradition' in Latin America for a single genetic entity to be released under different cultivar manes in different countries. It is a violation of the International Code of Nomenclature for Cultivated Plants (see http://www.ishs.org/sci/iracpcod.htm). CIAT not only tolerates, but actually encourages this practice, with the argument that it offers recognition to the various national research programs (who do the releasing). This is why you will generally find a list of several cultivar names for anything that is at all popular."

2.2.3 Varieties developed in the breeding program

There are six apomictic *Brachiaria* hybrids which CIAT already has, or might soon have that are slated for distribution. Four of these are still in early stages of development. Two are much further along:

- CIAT 36061: The original cross [cross number 625: *B. ruziziensis* clone 44-6 x CIAT 6297 (*B. brizantha* cv. Marandú)] was made in 1988.
- CIAT 36061 has been the object of negotiations between CIAT and a Mexican Seed Company (Semillas Papalotla, S.A. de C.V.). This is initially intended to be a research contract, with the purpose of evaluation of the hybrid by the seed company in order to determine if it has potential as a cultivar. If it indeed has commercial potential, then another contract would be signed involving royalties on seed sales (Carlos Lascano, personal communication).
- CIAT 36062: The original cross [cross number 818: *B. ruziziensis* clone 44-3 x CIAT 16829 (an accession very similar to cv. Marandú)] was made in 1990.
- CIAT 36062 displays exceptional antibiotic resistance to the spittlebug, and a general freedom from foliar problems or gross deficiency symptoms. However, it does not produce much viable seed, and is therefore only being slightly promoted in Colombia, by vegetative propagation (John Miles, personal communication).

Selected terms of the April 14, 2000 draft agreement between Semillas Papalotla, S.A. de C.V. (Papalotla) and CIAT (please refer to Appendix 10) include:

Commitments by CIAT

- CIAT grants to Papalotla the sole right for commercialization of Brachiaria hybrid CIAT 36061 in the USA, Mexico, Central America, and Panama, the Caribbean, and South America and China and Australia. The rights are granted for years (14?).
- CIAT will supply the necessary documentation, permission and all other pertinent information to permit Papalotla to register and protect this hybrid.
- CIAT will have the right to distribute the Brachiaria hybrid CIAT 36061 or their derived lines to other research collaborators worldwide, for evaluation and research purposes only.

Commitments by Papalotla

- Papalotla will adhere to CIAT Protocol II on Intellectual Property Rights, which is attached.
- Papalotla will be responsible for obtaining plant variety rights under their name in each country and their protection according to each country's law.
- Papalotla will pay CIAT a royalty of 2% (two) of all gross seed sales of Brachiaria hybrid CIAT 36061. This will be paid annually at the end of the year starting in 2000. Gross sales should include sales made to all Companies and organizations related to Papalotla.

2.2.4 Issues relating to FAO designation

According to Article 3 (Status of Designated Germplasm) of The Agreement Between the "Centro Internacional de Agricultura Tropical" (CIAT) and the Food and Agriculture Organization of the United Nations (FAO) Placing Collections of Plant Germplasm Under the Auspices of the FAO (Appendix 11):

- The Centre shall hold the designated germplasm in trust for the benefit of the international community, in particular the developing countries in accordance with the International Undertaking on Plant Genetic Resources and the terms and conditions set out in this Agreement.
- The Centre shall not claim legal ownership over the designated germplasm, nor shall it seek any intellectual property rights over the germplasm or related information.

Table 5, that summarizes the passport data (accession details) for the specific CIAT accessions utilized in the *Brachiaria* breeding program, contains three accessions which are not FAO designate germplasm:

- CIATFOR-16107
- CIATFOR-6780
- CIATFOR-26871

Daniel Debouck of CIAT's GRU has informed the Auditors that since the GRU intends to declare all materials received prior to December 30, 1993 as FAO-designated, these three accessions, all of which were received prior to that date, should be considered as FAO

designated germplasm (July 21, 2000 e-mail correspondence). Further to this, in an e-mail dated August 21, 2000, Dr. Debouck informed the Auditors that accessions 6780 and 16107 had been reconfirmed as designated germplasm in August 1999, as part of the periodical confirmation of lists to FAO.

During the course of the Audit the following question arose. If any of these accessions had been distributed prior to their respective FAO designation, and if they subsequently became FAO designated germplasm, would designation retroactive? Dr. Debouck replied to this query (August 22, 2000 e-mail correspondence) as follows:

> "Re. your question, my understanding is that the designation process has indeed retroactive effects. The second joint statement by FAO and the CGIAR states: "The Centres recognize that many accessions designated under the Agreements with FAO were distributed to plant breeders and researchers prior to designation in keeping with the CGIAR policy for providing "unrestricted availability" to germplasm - as noted in the Preamble of Agreements. In dealing with this situation, Centres will request and urge that no intellectual property rights be sought for designated germplasm that was distributed prior to its designation under the FAO-CGIAR Agreement". As you know, this statement was approved by the CGIAR at its Mid Term Meeting of (April or May) 1998 (thus negotiated between FAO and IPGRI on behalf of the CGIAR during the end of 1997 and early 1998), and reconfirmed at International Centers Week of 1998 (in November of 1998 if my memory is correct). The original agreement between FAO and the CGIAR about the in-trust collections was signed on 26 October 1994, and reconducted since. CIAT GRU did a designation process (somehow in hurry) in 1995, because of the Agreement FAO-CGIAR. There was a system-wide effort to reconfirm the lists of designated germplasms during 1999, and CIAT GRU sent lists of designated accessions for the three groups of commodities in August 1999 to IPGRI (putting all lists together and then passing them to FAO). So, this means that enforcement of MTAs goes back retroactively, and this is responsibility of a particular Center dealing with specific groups of germplasm."

Since, to the best understanding of the Auditors:

- All of the crosses in the *Brachiaria* breeding program have *Brachiaria ruziziensis* CIATFOR-26871 as a parent.
- It appears that this is the final accession used in the breeding program to obtain FAO designated status.

The retroactive effect of designation is potentially very important for this particular accession in the breeding program, as well as for the breeding program in general.

2.2.5 Issues relating to the United Nations Convention on Biological Diversity (CBD)

The CBD was established during the United Nations Conference on Environment and Development, popularly known as the Earth Summit, in Rio de Janiero, Brazil in June 1992 and entered into force in December 1993. Prior to the convention, genetic resources were considered to be a common heritage with no specific owner, and therefore, they could be utilized for research purposes without restrictions. The common heritage principle is a central tenet of the International Undertaking on Plant Genetic Resources and the FAO Commission on Plant Genetic Resources, both established in the1980s and involving some 135 countries. On the other hand, the CBD established that states have sovereign rights over their genetic resources and adopted the principle that a portion of the benefits stemming from the productive use of genetic resources should flow back to the nations that act to conserve and provide access to these resources. (Reid, http://www3.gencat.es:81). The CBD makes a definite distinction between benefits derived from the use of germplasm obtained before it came into force in December 1993, and material obtained after that date. The Convention is not retroactive and thus collections holders are not legally obliged to share any benefits with supplying countries from plant material obtained pre-CBD (see Wyse Jackson, 1997, http://www.rbg.ca/cbcn/en/newsletters/0104.html).

From an institutional perspective, CIAT, as with most of the other CGIAR Centers, has struggled with reconciling the terms specified for germplasm acquisition as defined in the CBD, which came into force in December 1993, and the FAO designation of germplasm. Protocol I-B of the CIAT Policy Statement on Intellectual Property Rights addresses this:

1. Any material acquired by CIAT after the UN Convention on Biological Diversity came into force will be received on the basis of terms previously agreed upon by the relevant donor country.
2. However, CIAT will request the country involved to agree to designate the materials under the Agreement with FAO.

Examination of accession details from Singer (SGRP), the CGIAR System-Wide Information Network for Genetic Resources, indicates that of the eleven accessions, comprised of three species, which have been used as parents in the CIAT *Brachiaria* breeding population, seven accessions of *Brachiaria brizantha*, and one accession of *Brachiaria decumbens* were collected from Zimbabwe, Ethiopia, Kenya and Uganda; two accessions of *B. brizantha* (CIATFOR-6780 and CIATFOR-6297) country sources are listed as unknown (both donated by Brazil in 1983); one accession of *Brachiaria ruziziensis* is listed with country source as "unknown" and donor country as "not applicable".

With the possible and critical exception of *Brachiaria ruziziensis* CIATFOR-26871, these accessions all appear to be FAO designated. Therefore, since they were collected prior to December 1993 they can be used in agricultural research and breeding purposes without restriction, i.e., are not bound by the provisions of the CBD. This situation would be totally different if the accessions had been obtained after December 1993, especially those donated by Brazil and Australia but obtained in other countries. The complexity of the source/donor relationship (due to the provisions of the CBD) would, under those circumstances, be compounded. Whereas one could argue that the present CIAT Brachiaria accessions, used in the

sexual breeding population, are not covered by the provisions laid forth in the CBD, some groups defend the position that progenies from two designated accessions are prohibited from IP protection. Again, this area is currently being debated and negotiated by international for a (CGIAR System and FAO) and CIAT should await the outcome of these high-level (and high profile) negotiations.

2.2.6 Coordination of activities between different units and programs at CIAT

During the course of the Audit, a situation of less than satisfactory inter-unit, inter-program communication within CIAT was brought to the attention of the Auditors. The central issues concerned CIAT registration of germplasm vs. FAO designation of germplasm, and FAO designation of germplasm vs. granting of commercial rights to such germplasm.

The specific situation regards CIAT 36061 (cited above). Whereas the GRU had intended, and was in the process of, registering CIAT 36061 as FAO designate, the TFP was (correctly, the Auditors believe) under the impression that CIAT and Semillas Papalotla, S.A. de C.V. were engaged in negotiations for a commercial contract which would grant Semillas exclusive rights to CIAT 36061. FAO designation of germplasm and the granting of exclusive commercial rights on a germplasm seem to be mutually incompatible an directly contradictory. Furthermore, the TFP was not aware that the GRU would (apparently) routinely follow CIAT registration of germplasms with FAO designation, unless there was an explicit request not to proceed.

The Audit, in this instance, was conducted in "real-time", in that it facilitated communication between concerned parties, and thereby circumvented a misunderstanding which might have otherwise resulted in an unpredictable outcome.

2.2.7 Discussion and Recommendations

Germplasm Issues Relating to the CIAT Papalotla Agreement

All germplasm that is released by CIAT is to be released under a standard MTA (Appendix 9) and is categorized as Designated Germplasm.

The CIAT MTA does not address the issue of germplasm progeny as it is impacted by FAO-designation. Indeed, there is still a significant worldwide debate on this point. When the debate is resolved, CIAT's policies and procedures regarding germplasm release and distribution may need to be reviewed in the light of that resolution. Such changes could significantly affect the terms of the CIAT-Semillas Agreement.

Recommendation 9:	**CIAT should designate a person responsible for monitoring developments under the CBD and FAO regarding FAO-designations**

A person should be specifically designated to ensure CIAT is well informed regarding the latest developments, and possibly contribute to the debate and negotiations with its expertise. Subsequently, the person should review all relevant policies and agreements to ensure consistency and compliance.

Since it appears that both parents of a CIAT 36061 are Designated Germplasm, then a recipient (including CIAT) may be prohibited, under terms of the Designated Germplasm MTA, from seeking (or offering) *any sort* of IP rights protection. Because CIAT 36061 is, by definition, progeny of its parents, it is unclear as to the obligations that a recipient (either CIAT or Semillas) may have regarding such hybrids if one or both parents are designated germplasm.

There appears to be a general understanding and compliance with the obvious and readily understood terms of the CIAT-Papalotla Agreement by CIAT. However, on a more profound level, the CIAT- Papalotla Agreement may not be internally consistent with CIAT's institutional goals. That inconsistency creates a high likelihood of misunderstanding among the parties regarding their respective rights and obligations. For CIAT's part, a faithful adherence to the CIAT- Papalotla Agreement in its current form, may, at a minimum, require significant modifications of some of CIAT's policies and procedures.

Recommendation 10:	**Review and possibly re-negotiate the agreement with Semillas Papalotla, S.A. de C.V.**

Because mutual trust is the most critical factor in any relationship, particularly between parties who are newly establishing their relationship, it may be valuable for CIAT and Papalotla to review the CIAT- Papalotla Agreement together, and if necessary to re-negotiate its terms.

Under the CIAT MTA for Designated Germplasm (Appendix 9), the recipient of such germplasm agrees "*...not to claim ownership over the germplasm to be received, nor to seek IPR over that germplasm or related information.*" Because the issue of germplasm progeny is not resolved, this provision may be at odds with those terms of the CIAT- Papalotla Agreement which grants certain sole or exclusive rights to CIAT 36061 by Papalotla.

Although an Audit of the CIAT-FAO Germplasm Agreement (Appendix 11) is beyond the scope of this IP Audit, CIAT Management is advised to review its obligations and their implementation under the CIAT-FAO Germplasm Agreement (Appendix 11). Specific areas for CIAT Management to monitor and adjust as appropriate:

Recommendation 11: Monitor and document the source of all germplasm used in breeding programs

It will be critical to monitor and document the source of germplasm that is used so that no conflict arises between the negotiated agreements pertaining to germplasm distribution and any other agreements that CIAT has made. Further, CIAT needs to clarify its stand regarding the germplasm progeny issues.

Recommendation 12: Establish clear policies on negotiation with non-CIAT parties to ensure consistency and compliance

Protocols need to be set in place to clearly instruct CIAT's negotiation team regarding the acceptable limits for negotiating agreements with an outside party. Following (or prior to) the signing of such an agreement, CIAT management needs to review the newly signed agreement and modify its internal policies and procedures to make them consistent with such an agreement.

Recommendation 13: Set in place a strategic response plan in the event that contract violations are alleged

Because contract violations can be alleged at any time, CIAT Management may prudently wish to develop a strategic response plan as part of their overall IP management proposal. This may require seeking the advice of an attorney who is well versed in IP law, employment law, and contract law matters.

Recommendation 14: Institute a coordinated policy for germplasm movement between GRU and other CIAT units

The Auditors recommend that CIAT institute a coordinated policy between the GRU and other units at CIAT, to facilitate designation/distribution of germplasm and progenies derived therefrom. Misunderstandings and possible misappropriations of germplasm can thereby be circumvented in a timely manner.

Additional Recommendations

2. It might be prudent for CIAT to further investigate the precise germplasm status of *B. ruziziensis*, determining if there exists any "paper trail" associated with the journey of this accession. This is particularly important since this species accession (CIATFOR-26871):
   - was obtained after a very long and circuitous route, having originated in the laboratories of the Catholic University of Lovain, Belgium. There is no known documentation

associated with that transfer. The Singer Germplasm Database refers to the Country Source as "Unknown" and the Donor Country as "Not Applicable." (It should be noted that CIAT the accession was transferred prior to the entering into force of the Convention on Biological Diversity and hence CIAT did not act counter to its own nor the CGIAR/FAO agreements or policies).

- appears to be, according to The Singer Germplasm Database, not FAO Designated Germplasm.

3. With regard to the use of multiple cultivar names used for individual accessions of *Brachiaria*, and CIAT's encouragement of this practice, CIAT may want to reconsider such a "policy", and attempt to standardize the cultivar nomenclature. This action would be consistent with International Code of Nomenclature for Cultivated Plants, and also be in harmony with the conventions outlined under the UPOV convention (UPOV Convention, Article 13).

Conclusions

This IP Audit of the *Brachiaria* breeding program (sexual crossing) represents an opportunity for CIAT to specifically address topics relevant to the *Brachiaria* program, and to generally evaluate managerial processes of CIAT germplasm in general. Critical components discussed herein can thereby be extrapolated to other crops and programs. Among some of the important components to consider are:

- accurate record keeping of accessions used as parental materials in any breeding program, and their status as to FAO designation; were they collected after the CBD went into effect in December 1993?
- advanced breeding lines and cultivar commercialization: Is this consistent with CIAT's policy on IP? Is this consistent with CIAT's policy on FAO-designated germplasm? Is this consistent with the mission of CIAT?
- coordinated and open communication between the GRU and other units within CIAT. This will facilitate implementation of the standard CIAT-wide policy on germplasm acquisition, utilization and distribution.

CIAT's consideration of these, as well as other, points, will undoubtedly serve to facilitate CIAT's mission and mandate.

2.3 FloraMap™: A Tool for the Conservation of Genetic Resources

2.3.1 Background

Under the pressure of a rapidly growing population and expanding economies, the earth's biodiversity is being eroded at an alarming rate. Among the threatened species are plants and beneficial insects that could hold the keys to food security, a safer environment, better medicines, and other areas that could improve the life of future generations.

Recent international agreements provide at least a framework for safeguarding biodiversity. In order to implement these, researchers need reliable tools for key tasks, such as determining where wild species of interest can be found, and once found, can be conserved. FloraMap™, the product of more than 20 years of research at CIAT, is one such tool.

FloraMap™ (www.floramap-ciat.org/floramap/requirements2.htm) was developed using Geographical Information System ("GIS"), a computer system capable of assembling, sorting, manipulating and displaying geographically referenced information i.e. data identified according to the locations. Using GIS it is possible to overlay maps, climatic data and plant species found in particular areas and establish a correlation between habitat, plant distribution and growth, among others. The climates at the points of collection of individual species is assumed to be representative of the environmental range of the organisms. Based on this assumption, FloraMap™ can be used to determine where wild species of interest can be found, their predicted distribution and the areas of possible adaptation when little or nothing is known of the species' detailed physiology.

With its user-friendly software linked to agroclimatic and other databases, scientists can use FloraMap™ to create maps showing the most likely distribution of wild species in nature. Such maps are extremely valuable for tasks such as planning collection expeditions and deciding where to locate programs for *in situ* conservation. Moreover it can be used as a tool to study the taxonomic and genetic variation of a particular species in a particular area, interrelate plant distribution with climatic conditions, map distribution of crop pests and their natural enemies in relation to the climatic condition and plan agricultural development in a certain area. Overall, it is also an important tool in research leading to the formulation of national policies.

FloraMap™ consists of climatic data and maps of various tropical regions of the world as data input, and a software to interrelate the map with climatic data and plant distributions. CIAT is distributing FloraMap™, in the form of a CD-ROM and Manual for a one-time payment of US$100.

2.3.2 Development of FloraMap™

The reason for having investigated the chronology of the development of FloraMap™ is related to the possible need to further document the origin of data that was inputted into the product over the years, particularly the terms under which such data was acquired.

Recommendation 15: CIAT should establish procedures for internally sharing essential research data

It is recommended that CIAT establish a protocol to follow when internal research data is shared among scientists between different divisions and/or projects. This should ensure that the possible ownership can be traced as and when required.

For practical purposes, there are two divisions at CIAT namely The Germplasm Division and The Natural Resource Division. Each division handles several research projects. The projects under the Germplasm Division are:

- IP-1 Improved Beans for Africa and Latin America
- IP-2 Regional Bean Networks in Africa
- IP-3 Improved Cassava for the Developing World
- IP-4 Improved Rice for Latin America and the Caribbean
- IP-5 Multipurpose Tropical Grasses and Legumes
- SB-1 Conserving Plant Genetic Resources of the Neotropics
- SB-2 Using Agrobiodiversity Through Biotechnology
- PE-1 Integrated Pest and Disease Management

whereas those of the Natural Resource Division are:

- PE-2 Overcoming Soil Degradation
- PE-3 Community Management of Hillside Resources
- PE-4 Land Use in Latin America
- PE-5 Sustainable Systems for Smallholders
- SN-1 Rural Agroenterprise Development
- SN-3 Participatory Research Approaches

There are two other projects which are organized across CIAT's divisions:

- SN-2 Partnerships for Agricultural Research and Development (overseen by the Director for Institutional Cooperation)
- BP-1 The Impact of Agricultural Research (overseen by the Director for Strategic Planning).

FloraMap™ was developed under the Agroecological Studies Unit which for a time was named the Land Use/GIS Program under CIAT's Natural Resource Division. However, in its early stages of development, the budget for FloraMap™ was provided under project SB-2 (Using Agrobiodiveristy Through Biotechnology), a part of The Germplasm Division. The movement of this project among CIAT's divisions may explain the general weakness of records regarding data sources. This same project, later known as FloraMap™ (also as the Geographic Information Systems project), was more fully developed under PE-4 (Land Use in Latin America).

2.3.3 The Development of FloraMap™

This Audit will review three phases of CIAT's GIS activities in the development of FloraMap™:

1. **Data input:** the data and databases used by CIAT to develop FloraMap™
2. **Software development:** CIAT's activities of algorithm development and manipulation, and
3. **The FloraMap™ product:** the released CD and accompanying Manual for Use

It should be noted that the Audit is limited in geographic scope to an analysis of IP protection issues of FloraMap™ within five countries and international law, as applicable. These countries of special attention for the Audit were determined in discussions between the Auditors and CIAT management.

1. Argentina
2. Bolivia
3. Brazil
4. Colombia
5. United States of America

Information obtained for the Audit was based upon communications with CIAT researchers, documents provided by CIAT, and documents/information which the Auditors obtained from various outside sources.

Data Input

Climatic data

The climatic data used in the interpolations of FloraMap™ were derived from SAMMDATA (South American Monthly Meteorlogical Data) which was initiated in the late 1970s and was maintained by Project PE-4. Later this climate database also included data from Asia and Africa, but the acronym was never changed. SAMMDATA itself was extracted from 144 different sources and was compiled over the 20-year period from 1978 to 1998. Some of the 144 sources were publications but much of the data came as data exchanges between CIAT researchers and other scientists. Details of the data sources of SAMMDATA are given in Appendix 12.

The sources of data included in the SAMMMDATA database can be categorized as follows:

- Primary data gathered directly by CIAT researchers
- Secondary data, including, data gathered by the meteorology institutes of various countries
- Tertiary data, including data obtained from scientific compilations of particular countries
- Quaternary data, an example would be data source number 128 (see Appendix 12) which was obtained from the International Rice Research Institute (IRRI). This data was obtained by CIAT from IRRI on a computer diskette containing climatic data for Malaysia which had

been gathered by the US Air Force 20th Weather Squadron. It is not clear what IP status this data has nor if there was an agreement in written form between IRRI and CIAT.

The Auditors attempted to determine whether the data included in SAMMDATA were obtained with documented permission and were used in accordance with the restrictions, if any, that were specified in such documentation. Further, the question was asked as to whether such data were properly cited as to source, when included in SAMMDATA.

It should be noted that in the process of FloraMap™ development, all the climate data included in the FloraMap™ has been modified and is in a different form than originally received. The climate surfaces are completely reworked data and none of the original data are present on the CD-ROM. In fact it would be very difficult to regenerate the original data from the surfaces. This is important since distributing the original data in a product such as FloraMap™ is more likely problematic whereas modified data does not present the same potential restrictions.

With the data having been compiled by many scientists over the period of over 20 years, the Auditors could not, in most cases, establish the permissions granted to CIAT for use and distribution of the data nor restrictions that may have been placed on the data. In this context, it is interesting to note an anecdotal account from one CIAT researcher that "data records (have literally been) written on the back on an envelope!! It really happens." (e-mail communications, September 18, 2000).

Recommendation 16: CIAT should establish procedures for receiving and sharing data from non-CIAT parties

It is recommended that CIAT establish a protocol to follow when researchers access non-CIAT data and when they share their data with outside entities. Care should especially be exercised when raw data sets are being exchanged. This should ensure that the possible ownership can be traced when and if it is required and should not be seen as a deterrent against sharing data.

A proposed draft for consideration by CIAT as prepared by the Auditors follows:

Centro Internacional de Agricultura Tropical (CIAT) is interested in receiving your or your organization's permission to use some of your or your organization's materials described below to be included for the improvement of FloraMap™, a software proprietary of CIAT, which will be distributed for research in biodiversity conservation and other scientific purposes.

Therefore, it is acknowledged by this document that you or your organization expressly grants CIAT permission to use those materials provided by you or your organization to be incorporated into the upcoming and subsequent versions of FloraMap™, in any form now known or later developed, without any obligations regarding royalty or payment for its use.

CIAT will be pleased to acknowledge you or your organization's material(s) in a suitable source credit line.

The materials supplied by you or your organization include (*Please initial all applicable items*):

continued...

_____

_____

_____

_____

You or your organization warrants that it owns and/or has the full authority and right to grant permission(s) to the material(s) offered and submitted herein.

If you or your organization agree with the foregoing, so indicate by having an authorized signatory for your organization sign in the appropriate place provided below. Return this original copy to CIAT and retain a photocopy for your files. On behalf of CIAT, we thank you and your organization for the assistance and contribution in the development of tropical agriculture research.

Prior to its execution, you or your organization have read the above and accept its conditions and agree to be bound by its terms.

Accepted and Agreed:

Individual or Organization Name: _____

Authorized Signature: _____

Printed Name: _____

Title: _____

Date: _____

Geographic data

The geographic coverage included in FloraMap™, such as locations of roads, rivers, political boundaries, cities and towns, are derived from the Digital Chart of the World (DCW) compiled by United States Geological Survey (USGS; see www.usgs.gov). The DCW consists of cartographic attributes and textual data stored on CD-ROMs with software that permits the database to be accessed, queried, and displayed on personal computers.

The DCW was developed by agencies that produce the Operational Navigation Charts (ONC) map series. These agencies are:

- the United States Defense Mapping Agency
- the Australian Army Survey Directorate
- the Canadian Directorate of Geographic Operations, and
- the United Kingdom Military Survey

These organizations were supported in the DCW design process by more than forty participating agencies. DCW, as produced by the USGS, is written in a special computer language which leads to the software ARC/INFO[1].

The USGS website states that the USGS of DCW is in the public domain. This means that the documents or data are not protected by copyrights and can be used by anyone.

This version is not always correctly georeferenced[2], hence it was difficult to use by CIAT. The Environmental Systems Research Institute (ESRI), a GIS company based at Redlands, California, began with the USGS version and did a considerable amount of cleaning and georeferencing to produce a proprietary ESRI product; the DCW-ESRI[3]. DCW-ESRI is available, on a licensed basis (Appendix 13), from ESRI in the form of 4 CD-ROMs for a fee of $395[4].

In the development of FloraMap™, geographic coverages from DCW-ESRI were used after heavy reprocessing to cut out excessive detail. Then CIAT used, in several cases, its own digitized maps, such as that for Latin America. Therefore, geographic coverages in the shapefiles[5] distributed with FloraMap™ are not the same with the originals from the DCW-ESRI.

Software development

The software in FloraMap™ was written using programming control from the software MapObjects™ LT (Appendix 14) which is a proprietary programming software of ESRI (Appendix 15), distributed royalty free at a cost of $100. The CD-ROM of MapObjects™ LT contains data and software. It should be noted, however, that the data from MapObjects™ LT was not used in the development of FloraMap™.

Production and Distribution of FloraMap™

The first production of FloraMap™ was done in 1998 when 20 copies of a Beta release were produced for review. In the further development, in January 2000, 500 copies of version 1 were produced. From the version 1 release, 100 copies were distributed as complimentary copies, 70

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1 ARC/INFO is Server based hybrid GIS software package, written and marketed by Environmental Systems Research Institute (ESRI). Comprised of Arc, the spatial GIS component and Info, a relational Database (www.geo.ed.ac.uk/agidexe/term?229)

2 To establish the relationship between page co-ordinates on a planar map and known real world co-ordinates (www.geo.ed.ac.uk/agidexe/term?1228).

3 www.maproom.psu.edu/faq/ques12.html

4 http://gisstore.esri.com/acb/showdetl.cfm?&DID=6&Product_ID=313&CATID=15

5 Shapefiles are a digital file format for geographic information. The files are the standard for ESRI and are used primarily with ArcView desktop GIS. They comprise 3 or 4 files with the same name and different extensions. One file has the actual x and y coordinates of the features. Another is a dbase file that holds the attribute information for each map feature. Another is the boundary information that says what the geographic extent of the data is.

copies of the CD were lost in transit and 100 copies were sold. Eighty-two users of FloraMap™ from all over the world have registered with the users group on a list server. CIAT is licensing the FloraMap™ for $100, and giving discounts for certain users based on application.

The major countries, with distribution, are as follows (certain other countries include one or two users only):

- USA (22)
- Mexico (8)
- Brazil (7)
- UK (7)
- Australia (6)
- India (5)
- Colombia (4)
- Germany (4)
- Belgium (3)
- Italy (3)

Related to the distribution of FloraMap™ is the following:

Recommendation 17:	**CIAT should study the possible implication of selling products (such as FloraMap™ or seeds) on its tax-exempt 501 (c)(3) status.**
This task should be delegated to an attorney well versed in tax-exempt status and accounting practices.	

2.3.4 Discussion on Specific IP Issues

Climatic data

Climatic data for FloraMap™ came from 144 sources of climate databases in various countries. However, as stated above, this Audit will limit its review to the impact of international law and the laws of Argentina, Bolivia, Brazil, Colombia, and the United States on the development of FloraMap™.

All of these counties are members of WTO which, under TRIPS[6], have to ensure a certain level of copyright protection as agreed under Copyright Law. Databases are protectable under Copyright Law. 157 countries in the world including Argentina, Bolivia, Brazil, Colombia and the United States are signatories of WIPO's (World Intellectual Property Organization) Copyright Treaty of 1996[7]. The Treaty extended copyright coverage to computer programs and databases. Noteworthy is that "*this protection does not extend to the data or the material itself*

[6] www.wto.org/english/tratop_e/trips_e/intel2_e.htm

[7] www.wipo.org/eng/main.htm

and is without prejudice to any copyright subsisting in the data or material contained in the compilation" (Article 5). However there are certain limitations in the protection, afforded under Article 10, which can be defined by and enacted in the respective laws of each country.

Under WTO, TRIPS stipulates essentially that the same level of protection has to be afforded to data and databases. Developed country members have had to comply with all of the provisions of the TRIPS Agreement since 1 January 1996. For developing countries, the general transitional period was until 1 January 2000. Bolivia, Colombia, Argentina and Brazil are all considered developing countries under WTO.

The Copyright Laws of Argentina, Bolivia, Brazil, and Colombia, are based on the directives of WIPO's Copyright Treaty and the TRIPS agreement. Copyright law in the respective countries differ only in the wording, but the content is essentially the same.

For the countries under study, the copyright law as pertaining to databases and data sets can be summarized as follows[8]:

1. Databases are protected, the protection covers the form of arrangement and expression of the data, insofar as the selection or arrangement of the contents constitute an intellectual creation.
2. The protection of databases does not extend to the data or material itself.

In the case of climatic data for FloraMap™ it is clear that:

- Climatic data and geographic data are data, which are not covered by protection of databases per se.
- All the climate data included in the FloraMap™ has been modified and presented in different forms than previously received when originally placed into SAMMDATA.

According to the two arguments presented above, it is likely that the inclusion of the climatic data used to produce FloraMap™ was not included in violation of international treaty for copyright and the laws of Argentina, Bolivia, Colombia, Brazil and USA. However, it is not clear whether certain data was acquired under restricted terms which would make their further use in FloraMap™ subject to such restrictions.

Geographic coverages

The geographic coverages of FloraMap™ were derived from the DCW ARC/INFO version from ESRI. The license agreement of the DCW-ESRI (Appendix 13) lists several terms of relevance here (emphasis added):

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[8] **Argentina**: Presidential decree 165/94.
Bolivia & Colombia: Decision 351 of Cartaghena Agreement.
Brazil: Law No 9610 of February 19,1998 on Copyright and Neighboring Rights.
USA: Copyright Law of the United States of America and Related Laws: 17USC§102.

- This is a license agreement, and not an agreement for sale, between the user (Licensee) and Environmental Systems Research Institute, Inc, a California corporation, which its principal place of business at 380 New York Street, Redlands, California, 92373-81000.
- This Digital Charts of the World for use with ARC/INFO® Software License Agreement (Agreement) gives Licensee certain limited rights to use the Database and Related Materials. All rights not specifically granted in this Agreement are reserved to ESRI.
- Permitted uses:
  - Licensee may install the Database or portions of the Database on to permanent storage device(s) and reproduce a corresponding number of copies of the Related Materials for Licensee's own internal use.
  - Licensee may make only one (1) copy of the Original Database for archival purpose unless the right to make additional copies is granted to Licensee in writing by ESRI.
  - Licensee may modify the Database and merge other data for Licensee's own internal use. The portions of the Database merged with other data sets will continue to be subject to the terms and conditions of this Agreement.
  - Licensee may sell, market, or otherwise distribute published hard copy renditions of the Database or derived portions of the Database, provided that the Licensee includes a legend statement acknowledging ESRI as the source of the portion(s) of the Database that is displayed, printed or plotted.

- Not permitted uses:
  - Licensee shall not sell, rent, lease, sublicense, lend, assign, time-share or transfer, in whole or part, or provide unlicensed third parties access to the Database, Related Materials, any updates or Licensee's rights under this Agreement.
  - Licensee shall not reverse engineer, decompile, or disassemble in an attempt to duplicate the proprietary and copyright-protected ESRI ARC/INFO format.
  - Licensee shall not remarket or distribute the Database or any derived Database portion in digital form to unlicensed third parties.
  - Licensee shall not remove or obscure any ESRI copyright, proprietary or trademark notices.

The IP issues in the use of DCW-ESRI in the FloraMap™ are as follows:

1. There is no legend statement acknowledging ESRI in the FloraMap™ Manual as the source of the geographic coverages.
2. The files distributed with FloraMap™ are not the originals from the Arc/Info version. They have been heavily reprocessed to cut out excess detail, although the actual points that remain are the same coordinates as some of the original data. The use of FloraMap™ is not in conjunction with the use of DCW ARC/INFO from ESRI, because FloraMap™ can not be used to draw or plot or print maps of the world similar to those of the DCW ARC/INFO. However, in the license terms it is specifically stated that *"licensee is not permitted to remarket or distribute the Database* or any derived Database portion in digital form *to unlicensed third parties"* (emphasis added). Since the geographic coverages of FloraMap™ can be viewed as the derivation of the portions from DCW-ESRI, and CIAT is distributing

FloraMap™ to third parties, it is advised that CIAT seeks permission from ESRI regarding this matter.

Recommendation 18: CIAT should re-negotiate the agreement with ESRI or develop an alternative strategy

The licensing agreement should be renegotiated, paying particular attention to these points:

- the right to install more than one copy of the original database onto CIAT's servers
- CIAT's failure to comply, to date, with ESRI's requirement to place certain language on all hard copy renditions of the database
- the license requirement not to (pertaining to renditions or derivatives of the database) "sell, rent, lease, sublicense, lend, assign, time-share or transfer, in whole or part, or provide unlicensed third parties access to the Database, Related Materials", which CIAT violated in the production of FloraMap™

It should be noted that a renegotiation of the contract is not the only option; others could be developed and will depend on the relationship between CIAT and ESRI, and on the long-term relationship that CIAT wishes to develop.

Also, as will be discussed below, the copyright permission and release form signed by CIAT for ESRI is a standard form at ESRI for the copyright and release form of materials acquired by ESRI from third parties. However, the term "use" is very broadly defined and may not be suitable for the purpose of the use of FloraMap™ as an advertisement for MapObjects LT.

Software development

The software used in the FloraMap™ is written using programming control from Map Objects™ LT, a software from ESRI. ESRI licenses the software royalty free with certain restrictions contained in their License Agreement (emphasis added):

- License section of "Data":

  Data: NOTE that there are RESTRICTIONS ON DISTRIBUTION OF SOME OF THE DATA on the Maps and Data CD. Some of the data on the maps are licensed by ESRI from third party suppliers and may only be distributed in compliance with the distribution rights section of the on-line Data help files.

- Copyright notification of MapObjects LT:

  Trademark, Copyright and US Government Rights Notice: MapObjects LT is copyrighted by Environmental Systems Research Institute, Inc. All rights not specifically granted in this License are reserved to ESRI.

You (the Licensee) may use on one computer per Map Objects LT License to create maps and mapping functionality and distribute them without being obligated to ESRI for royalties or any payment beyond the Map Objects LT License fee.

You Must Include the Following Notice in All Documentation and in the Applications On-line Help or Read Me File: "Portions of this computer program are owned by Environmental Systems Research Institute, Inc. Copyright © ESRI, 199_ . All Rights Reserved. Use, duplication, and disclosure by the U.S. Government are subject to restriction set forth in FAR § 52.227 – 14 alternate III (g) (3) (Jun 1987) , FAR § 52.227 – 19 (JUN 1987) and/or FAR §12.211/12.212 [Commercial Technical Data/Computer Software] , and DFARS § 252.227-7015 (NOV 1995) [Technical Data] and/or DFARS § 227.7202 [Computer Software], as applicable. Contractor/Manufacturer is Environmental Systems Research Institute, Inc., 380 New York Street, Redlands, CA 92373-8100 USA. Some data are provided by GDT, Copyright Geographic Data Technology Inc. All Rights Reserved."

You Must Include the Following Notice on All Media, Packaging and Documentation for Your Application: MapObjects is a trademark for Environmental Systems Research Institute, Inc. Copyright © 199_ Environmental Systems Research Institute, Inc. All Rights Reserved.

There are two issues regarding software development:

1. The Data section notification (section 1) does not apply to FloraMap™ because in the development of FloraMap CIAT researchers did not use the data. Instead, they are only using the ESRI built programming controls.
2. In the documentation or software of FloraMap™ the notice above (section 2) is not included.

Recommendation 19:	**Future version of the FloraMap™ Manuals should be revised to include appropriate references to ESRI software**

Distribution

There are several IP issues related to the FloraMap™ as follows:

1. Previous distribution of FloraMap™
2. Use of FloraMap™ on ESRI's website
3. Registration of FloraMap™ as a trademark
4. Preventing any non-CIAT entity from copying and selling FloraMap™

1. Previous Distribution of FloraMap™

At present FloraMap™ is distributed as a standard commercial software with a fully paid up license for a fee of US$100. The Manual of FloraMap™ cites license terms as follows:

- "The enclosed software is a proprietary product of CIAT, and protected under US copyright law. The software may be used only by computers owned, leased, or otherwise controlled by you. Neither concurrent use on two or more computers nor use in a local area network or

other network is permitted without separate authorization and the payment of other license fees. You agree that you will not assign, sublicense, transfer, pledge, lease, rent, or share your rights under this License Agreement. You agree that you may not reverse assemble, reverse compile or otherwise translate the software.

- Upon loading the software into your computer, you may retain the program diskettes for back up purposes. In addition, you may make one copy of the software on a second set of diskettes (or on cassette tape) for the purpose of back up in the event the program diskettes are damaged or destroyed. You may not copy the user Manual or parts of the user Manual. Except as authorized under this paragraph, no copies of the software or the user Manual may be made by you or any person under your authority."

According to CIAT's mandate, client countries are encouraged, particularly in the developing world, to use its products. Hence it is questionable whether the above license is appropriate and consistent with CIAT's policy.

Recommendation 20:	**Harmonize distribution of FloraMap™ with CIAT's policy or adapt CIAT's policies to its current practices**
Both the license and license fee imply that CIAT is distributing FloraMap™ as a commercial product which may not be in accordance with stated CIAT policy.	

2. Use of FloraMap™ as an advertisement on ESRI's website

FloraMap™ is being used as an example of a product which can be developed using MapObjects LT (Appendix 14). For this purpose, CIAT signed a copyright permission and release form with ESRI which states (Appendix 16):

- "Therefore, it is acknowledged by this document that you or your organization expressly grants ESRI and its successors and assigns a personal, nonexclusive, nontransferable, irrevocable, worldwide, royalty-free, perpetual right, license, and privilege to use, copy, adapt, edit, modify, merge, reproduce, (re)print, (re)distribute, (re)broadcast, (re)transmit, and publicly display and/or perform the material(s) provided by you or your organization that are incorporated into the upcoming and subsequent editions of ESRI Work, in any form now known or later developed, and to claim any rights, title, and interest in the overall ESRI Work. ESRI will be pleased to acknowledge you or your organization's material(s) in a suitable source credit line and proprietary rights attribution supplied by you or your organization."

3. Registration of FloraMap™ as a trademark.

During the Audit it was found that CIAT intends to register FloraMap™ as a trademark both as typed drawing and as a logo in the USA. Initial searches had been performed for CIAT by Trademarks Etc. (Appendix 17). However, when the Auditors checked TESS (Trademark Electronic Search System) (Appendix 18), it was found that FloraMap is only registered as a Mark Drawing Code (1) (Typed drawing), i.e., only the word "FloraMap" and not the logo was registered.

Recommendation 21: **CIAT should fully trademark the word "FloraMap" together with the corresponding logo to prevent being blocked from use by a non-CIAT party**

Following discussions with CIAT, ISAAA submitted an application to the US Patent and Trademark Office, on behalf of CIAT, for the word "FloraMap" and its logo as trademarks (Mark Drawing Code (3): Design plus words, letters and numbers).

This word-mark "FloraMap", however, is not owned by CIAT, but rather the owner is CIAT's former Director General, Dr. Grant Scobie. This should be rectified. CIAT has at least two options:

1. Go back to the Trademark Office, and inform them that the owner is not a true representation of the client. The application might thereby be changed by the Trademark Office. However, there are several potential drawbacks to this approach. The Trademark Office might, out of due process, view this as a change in the application, and therefore require another fee of $320.00. This would also re-zero the clock for the statutory period for review (that is, back to 12-18 months pending registration).
2. Retain Grant Scobie as the owner of the mark, and then execute an assignment agreement between Grant Scobie and CIAT.

Recommendation 22: **CIAT should ensure that the type drawing trademark of "FloraMap" is in CIAT's name rather than in the name of one of its former Director General**

Depending on the relationship between CIAT and its former Director General, executing an assignment agreement might be the easiest option.

4. Preventing any non-CIAT entity from copying and selling FloraMap™

At present CIAT distributes FloraMap™ under a commercial software license. One CD-ROM FloraMap™ is sold with a Manual for US$100. If the demand for the product increases, a hypothetical software pirate could copy FloraMap™ for $0.30 per CD (plus Manual; which could also be put on the CD) and sell the product at a much lower cost than CIAT. At present, the product is copyrighted and the trademark has been sought in the USA only.

Most countries in the world have copyright laws (see footnote 8 above), and because the main value of the FloraMap™ CD-ROM is in its software, databases and maps (and the algorithms and interface by which it is extracted), the content could be protected. Under most country's laws, this would make it illegal for any third party to copy and sell CD-ROMs containing protected material per se. The mechanism by which copyright is sought for each country would have to be determined. It should be noted that copyrighting the product would block the possibility that a non-CIAT entity could copyright it.

On the other hand, because CIAT sees its mandate to make information and tools available to all that need it and will use it, it may be argued that there is no reason for CIAT to want to prevent an alternative distribution channel from being developed.

CIAT essentially has two options to proceed with the copyright issue:

1. Imprint the copyright symbol "©" on the CD-ROM and the Manual (as CIAT has done).
2. Register the copyright (which is useful if and when a dispute arises) in a wide range of countries where FloraMap™ might have value.

Recommendation 23:	**CIAT should consult with its attorney and study the pros and cons of registering the copyright of FloraMap™ in countries where the product has potential value**

Future distribution of FloraMap™

Recommendation 24: CIAT should consider changing the licensing terms of FloraMap™

While it is not against CIAT's mandate to sell commercial products, it may be advisable for CIAT to distribute FloraMap™ as a "non commercial software" by modifying its website and Manuals to include statements to the following effect:

1. The distribution of FloraMap™ is for non-profit purposes only.
2. "Price" is charged to "contributions toward production and distribution costs".
3. Clearly stating that FloraMap™ is distributed free from any restrictions on subsequent use, sale, or distribution.
4. Clearly state the offered discount for scientific and training purposes and/or a discount to selected countries.

Whereas these options might be considered "creative", they do not, however, fundamentally address the issue of selling products.

2.4 Laboratory Notebook Policy

2.4.1 Background

CIAT is entering a new era. It is considering protecting its own inventions and is engaging in research with other organizations, both public and private. These new relationships, often based on collaborative research agreements, may require precise documentation of certain activities and results. Laboratory and research practices will frequently need to be carefully formalized and noted in ways that will allow Auditors to review the authenticity of results and certify the dates of occurrences. Such practices are important also for potentially patenting possible discoveries made by CIAT or a CIAT collaborator, especially when seeking patent protection in the USA under the "first to invent" concepts that govern patent law in the USA.

Recording procedures are generally spelled-out in *Laboratory Notebook Procedures.* These procedures inform all staff about the process for daily establishing and maintaining laboratory records that could become primary evidence for the resolution of disputes or litigation. In court, dates of invention, description of an invention, and research techniques can be established through adequately established laboratory notebooks.

In order to achieve such goals, a bound laboratory notebook, in whatever format, must be:

a. an honest representation of the research work done by the researcher,
b. regularly written (daily recording is normally recommended),
c. routinely witnessed (at least weekly) by another scientist,
d. duplicated when completed, if the researcher would like a working copy, and
e. the original laboratory notebook archived in a secure place or by a secure method.

The Auditors have prepared a proposed laboratory notebook policy draft, offered below, to guide CIAT in the development of its own policies and procedures. These policies and procedures can be significantly modified to suit CIAT's needs and to harmonize with other CIAT protocols. It is essential, however, that any laboratory notebook policy be consistent with other laboratory procedures, that CIAT staff be well trained in the execution of the policy, and that the adopted policies be systematically enforced.

2.4.2 Proposed Draft for Considerations

Policy

The purpose of this policy is to ensure that CIAT is sufficiently protecting its inventions, research, and products, so that discussions or allegations during disputes or litigation are based on documented fact. This includes such things as the date of an invention or a description of the invention or research, the dates or research techniques that were used can be proven without a doubt, and the like. In order to do this, the "laboratory notebook," in whatever format, must be an honest representation of the research work done by CIAT, and must be acceptable to a court, the

US Patent and Trademark Office and other offices whose charge is regulating statutory protection of IP. Therefore, certain standards apply to each type of notebook.

Guidelines

1. GENERAL

All ideas and data must be entered into a laboratory notebook. Entries must be complete enough that another scientist would have little or no trouble understanding and repeating the experiments.

Each page must be signed by the scientist running and recording the experiment and dated each day, and signed and dated by a witness, if not immediately, then at least within one week of the scientist's signature.

2. LABORATORY NOTEBOOK TYPES

In deciding the exact procedures to follow, it is important to remember that any type of laboratory notebook must achieve two goals:

a. show its own integrity, and

b. corroborate the information independent of the person doing the research.
Thus, the laboratory notebook must demonstrate that it has not been tampered with by reflecting any changes made and demonstrating that no pages have been deleted or added without any such change being evident and the old information being capable of being compared with any new information. A witness, independent from your experiment, must attest that the information, experimentation, and/or ideas that occurred were recorded on the date indicated.

A. Hardbound laboratory notebook

Laboratory notebooks are checked out from __ **name** __ in the __ **location** __ and returned to __ **name** __ immediately upon being filled, to be microfilmed.

When signing out a new laboratory notebook, you will notice that your laboratory notebook is numbered, is permanently bound, has index pages and that all pages are pre-numbered.

Enter a new experiment in the index each time you start a new experiment.

Use each page in order. Leave no blank pages between experiments.

Record enough information so that a scientist "skilled in the art" could pick up your laboratory notebook and easily determine what had been done, why it had been done and what the results were. Entries should include procedures, reagents, lot numbers where appropriate, sketches, descriptions, etc. The purpose and significance of the experiment as well as observations, results and conclusions should be made clear. Remember, what may seem trivial or obvious at the time your experiments are conducted, may later be of critical importance.

If you have already described your experiment in an earlier experiment, or if you use a standard protocol and you have not deviated from the previous descriptions of the experiment for your current one, you may reference the earlier information instead of writing it out again. For example, if you are starting a new experiment on page 42, and are using the same protocol as already described on page 25, write on page 42, "Following the protocol as described on page 25 of this laboratory notebook...."

Enter all data, in ink, directly into the laboratory notebook.

Corrections should be made by drawing a single line through the entry. Never use erasers or whiteout. Initial each lineout, and if possible, put in a note of explanation next to each lineout, such as, "wrong data." Never tear an original page out of your laboratory notebook. Pages may be copied for your own benefit, but never removed.

At the end of each day put a line or a cross through any unused space on that day's page(s) in the laboratory notebook. If you normally leave a blank line between paragraphs, don't lineout that one line, but if you have a number of lines left on the bottom of the page, line them out. This will prove that you are unable to enter additional information in the laboratory notebook, in those empty spaces, at a later date.

If additional information, such as a machine generated table or graph, an original photo, autorad, etc., is part of your experiment and is small enough to be attached in your laboratory notebook, do so using glue or non-removable tape, thereby permanently attaching it in your laboratory notebook. Then sign your name over the border of the original photo, etc., crossing over onto the laboratory notebook page. Your signature will cross over both the picture, etc., and the laboratory notebook, thereby clearly showing at any time in the future that the picture has been removed.

If your additional data is too large for your laboratory notebook, i.e., a computer printout that is a few pages long, such additional data can be signed, dated and countersigned and dated by your laboratory notebook witness and given an appropriate ID number. You should also note on such additional data which laboratory notebook and which page number the additional data is referenced. Then in your laboratory notebook you should reference the additional data's ID number and note the storage location where the additional data is being securely held. Preferably, a drawer with a set of files that are always used to store oversized information should be used. A summary of the data can be placed in your laboratory notebook. The same sort of procedure should be followed with any samples that are to be kept.

Each original page of your laboratory notebook must be signed and dated by you and by a witness. A witness should be someone who has read each entry, who is competent to understand what s/he has read, but who is not a co-inventor. Each research group should designate a person who is responsible for assigning permanent witnessing partners. However, if your assigned witness is not available when needed, you may use another person who fulfills the above criteria.

If any changes are made after the pages are signed or witnessed, the changes must be initialed and dated by both you and a witness. Always use the current date when signing or witnessing a laboratory notebook.

Use the laboratory notebook to record ideas, as these may be important in determining a date of invention.

It is important to return completed laboratory notebooks to __ **name** __ as soon as possible to ensure a duplicate copy of the laboratory notebook is captured on microfilm or other permanent media. This process will take no longer than __ **time period** __. A laboratory notebook can be retrieved at any time during the microfilming process if needed. Upon completion of the microfilm process, the laboratory notebook will be returned to the researcher for use as reference in the laboratory or put into permanent storage per the researcher's request. Please note that one microfilmed copy will be kept in the library for access at any time. One other copy of the microfilm copy will be put into secured storage at the __ **storage location** __.

B. Hardbound Notebooks supplemented with data that has been electronically captured:

This refers to laboratories where a large amount of data is generated and stored in the computer. This method still requires a written laboratory notebook with all of the guidelines referred to above. The difference is that much of the data referenced to in the laboratory notebooks may be in electronic files. The laboratory notebooks should contain a summary of the information in those files, and also give the location of the computer file (the file name) under which this data is stored.

Such electronic data should be backed-up and archived weekly. A new and separate file should be provided as a place to store data. Details of these files and the back-up procedure should be described to all researchers and managers in an attached memo. These backed-up files should never be opened except for litigation or Patent Office matters.

C. Hardbound Laboratory Notebooks generated by computers:

The same guidelines apply as for the hardbound laboratory notebooks. The difference is that rather than purchasing a laboratory notebook and writing in it, the written material is generated electronically. This is printed out on a regular basis, depending on the size of the printout, and then bound to form a laboratory notebook. The printed material should be clearly labeled with the information that will appear on the front of the bound book and sent to __ **name** __ for binding. Once bound, the laboratory notebook will be assigned a number, recorded and returned to the researcher or archived upon request.

Each experiment is to be described and each page should be numbered and signed, countersigned, and dated. Each week these experiments are to be saved in the special data file as described in the attached memo. Also, as above, data such as small graphs, photos of gels, etc., which can be attached to the laboratory notebook page should be done so as described above, in a permanent manner.

Even though this may be a very handy way of recording experiments, it is not the preferred way, for a variety of reasons. For example, if a number of experiments from different days are printed on one page, and the page is only signed and dated after the last entry, thereby giving rise to the suspicion that all the work was done as of the date of the signature. This could cause a problem with pinpointing an exact date of invention.

Additional Comments

Avoid sweeping negative statements such as "This procedure is worthless" or "we infringe X's patent with this procedure." If an experiment appeared not to give the expected result, a short discussion of why you think this happened and what could be done to follow up on the result should be made. Comments on infringement should never be made.

Your laboratory notebook and its contents should be considered confidential and of great value. Laboratory notebooks should be stored in a secure place when they are not in use. Report the loss or theft of your laboratory notebook to your supervisor immediately.

Completed laboratory notebooks that have previously been microfilmed and are no longer needed as reference in the laboratory should be returned to __ **name** __. These laboratory notebooks will be recorded as returned, and stored in a secured location.

When an employee leaves CIAT, laboratory notebooks signed out and used by that person should be returned to the central location, whether or not all pages have been totally filled out. Depending on the number of blank pages remaining, this laboratory notebook may be signed out and used by another scientist. For example, if a summer intern, visiting scientist, or other visitor has used only three pages of their own laboratory notebook, when that person leaves, the laboratory notebook should be returned to __ **name** __, who records that s/he received it, and s/he can then sign it out to the next person needing a laboratory notebook, and record the new owner's name in his/her files.

Keep your laboratory notebook as if each project were to be patented. Even though the work contained in the laboratory notebook may not result in a patent application, observance of these rules will provide a clear record for reports and publications.

Audits will be conducted continuously by various designated people, both in your group and from other groups, to ensure that the laboratory notebook policy is being adhered to correctly.

If you have problems fitting your procedures to these, please contact your patent attorney.

Computer Back-up for Notebooks

The IM (Information Management or appropriate name for CIAT's computer group) and Legal department should develop an archiving strategy for data in electronic form that helps satisfy legal concerns for IP protection and complements the existing bound paper laboratory notebook system.

At weekly intervals, a "snapshot" of all the data in __ **CIAT's research computers** __ should be copied to a CD-ROM disk. The contents of the __ **patent directory files** __ directory will be deleted after the copy is made. This CD-ROM disk will be stored in a safe vault, accessible on an as-needed basis by the Legal Department. Over time, then, __ **CIAT** __ will have time-dated snapshots of all this data, on a medium with a very long life.

3. DISCUSSION AND CONCLUSIONS

3.1 Introduction

"Keep your eye on the goal and understand the rules." This advice, from a world-class hockey player, arguably may apply to CIAT activities and endeavors regarding PP management (PP, comprising intellectual property (IP) and technical property and related information (TP)) because at no time in CIAT's history have the two–the goal and the rules of the game–been faster changing and been more difficult to reconcile. The very fact that CIAT works with public money for the public good makes it critically different from a private entity which works with private capital for private benefit. The ultimate goals of the two institutions–benefiting the end-user–are essentially identical since a private entity can only survive if the end user captures a significant portion of the benefits.

The rules of the game, however, or the way this can be achieved are intrinsically different. In that context, the advent of biotechnology in particular, and with it proprietary aspects of science, push CIAT enter into realms of what had previously been reserved primarily to the private sector. Hence, business as usual is no longer feasible if CIAT wants to take advantage of proprietary (not public) science.

For CIAT, its goal is clearly stated in its mission statement, "To reduce hunger and poverty in the tropics through collaborative research that improves agricultural productivity and natural resource management." The rules of engagement, however, are rapidly changing in the international scene and this may make success more elusive. Increased emphasis on PP rights management, increased investments in ag-biotech by the private sector as well as international treaties such as the *Convention on Biological Diversity* and GATT/TRIPs have altered the options for public organizations like CIAT. These same forces are also shifting the framework for CIAT's clients, the NARS and the poor farmers in developing countries.

In order to disentangle the complexities of IP management, it is useful to separate three types of activities of CIAT (let's call them the three steps). The **Initial Step** is access to technologies (information, germplasm, biotechnology, etc.). The **Middle Step** is work performed within CIAT. And the **Final Step** is the distribution of its technologies (be they in the form of improved germplasm or data or information or know-how) to its clients.

- **Initial Step**: obtain, preserve, use and distribute germplasm and information and know-how as well as those biotechnology, laboratory tools and data and components that are needed to produce improved CIAT mandated crops and to improve agricultural management systems;
- **Middle Step**: develop and produce improved germplasm (intermediary or finished) and agricultural management systems through scientific and technical "value added" research, processes and discoveries; and
- **Final Step**: enable the release of improved germplasm and related information, and develop and share better agricultural management systems, by national programs to farmers in developing countries, primarily poor farmers, whose lives are thereby improved.

To reach its goal more effectively, CIAT has recognized the need and value for strengthening its relationships with "upstream" partners, particularly those with the private sector. CIAT has made significant strides in introducing such activities as collaborative research agreements and similar interactions. Further, CIAT has recognized value in making alliances with "downstream" partners in the private sector as well.

There are several reasons for initiating partnerships with the private sector. Principal among them is that the private sector owns the majority of the pieces of any of the biotechnological applications; technologies that hold so much promise for the entire range of CIAT clients. Further, as developing country seed companies begin to expand their influence, they can bring improved seeds to CIAT clients. While in the past, relationships between private sector entities and public ones, like CIAT, have been quite limited, in the future such relationships may be absolutely critical for success in CIAT's future.

Similarly, to disseminate its technologies more effectively and within the confines of the changing international IP regime, CIAT has adopted practices of protecting its own products and inventions. These practices have been implemented on an *ad hoc* basis and will need to be formalized, not least because to the outside world and private collaborators, the current strategy of CIAT is rather unpredictable since formal policy elements have not been defined adequately and implementation strategies are not coherent. This makes it difficult to develop relationships of trust and mutual confidence in the long term.

Relationships, whether at a personal level or between institutions, are built on mutual trust. Strong relationships are nurtured and sustained by the ability of each partner to understand and supply the needs of the other partner. Through the vehicle of agreements, organizations define how they will interact. For CIAT to be able to successfully collaborate with private sector organizations, it must understand what the private sector "needs," and what the private sector "wants." Then CIAT can establish the cost involved (monetary or non-monetary costs), compare the pros and cons of different strategies, judge the relative value of different alliances, and determine whether or not such collaboration takes it closer to its goal. Thus, proprietary property rights management issues are less about "legal" documents than about building, strengthening, and maintaining relationships.

As the Auditors spoke with various CIAT staff members they were impressed by the overall interest in and knowledge about IP related aspects and the keenness with which CIAT staff and management was entering into this new and uncharted area. At the same time, the Auditors recognized a phenomenon common in any institution, namely that a range of staff members had reservations about new constraints imposed by PP rights management. These reservations were often based on a lack of understanding about how such agreements can be used to serve the purposes of the organization and thus of projects. At CIAT such manifestations generally fell into four broad areas:

- a superficial understanding of the limits imposed on CIAT and non-CIAT research use of germplasm (Designated *vs.* Non-Designated).
- the loose interpretation and understanding when distinguishing between "research" and "commercial" licenses as applied to various biotechnology or germplasm components.

- the production of unlicensed laboratory chemicals as a cost-saving measure, which is legally and ethically defensible if the chemical is not patented in the country where it is used (which was the case in certain examples analyzed during the Audit) but which may become a major stumbling block if a statutory protection is sought on subsequent discoveries.
- the feasibility of acquiring data from and the circumstances under which certain data can freely be obtained, used, reproduced and distributed.

Whereas IP management does indeed present CIAT with new constraints, it also generates new opportunities not previously available to an international research center. *Golden*Rice™ in this context is a good example to cite. As a product it is entangled in a myriad of technical and IP constraints. Still, the inventors made it clear during a speech given at the World Food Prize in Des Moines (October 2000) that their invention would not have been possible had it not been for the wealth of discoveries made, and published, by the private sector, and certain TP to which they had ready access. In a world where discoveries by the private sector are not always readily protectable, corporations might (most likely would) resort to trade secrets and thereby not disclose their inventions. As it is, companies are encouraged to disclose their inventions and, in order to optimize their revenues, license out discoveries to any institution that can add value to their inventions. Such out-licensing may provide the corporations with returns that are not necessarily monetary.

In a perfect world, with unlimited resources, institutions may solve their problems in these areas by "throwing money" at the problem. An easy solution would be to hire additional personnel, call for staff training, authorize additional management positions (General Counsel, Director of Licensing, etc.), and add managers throughout the institution to assure that everything is done "according to Hoyle."

Of course, in the real world of diminishing budgets and limited resources in which CIAT lives, such changes, if made, would further reduce the number of research and product development positions; the very critical Middle Step in CIAT's goal-directed pathway. Therefore, a resource-rich solution seems an impossibility for CIAT.

Yet, CIAT is faced with the need to show that it has mastered PP rights management, if for no other purpose than to inspire trust and confidence in the private sector. Only a "predictable" CIAT will gain and maintain the trust of the private sector. Further, CIAT must master PP rights management and do so in an economical and efficient way in order to satisfy its donors' perceptions and goals.

As the Audit was conducted, projects at each of CIAT's three goal steps were analyzed (some Audited projects bridged more than one step). Audit observations from these projects are discussed below. First, we present a synthesis of major recommendations based on the projects analyzed, followed by a more generic discussion and recommendations from a management perspective.

3.2 The Audit: Review of a Cross-Section of Projects

It should be emphasized at the outset that the Audit was designed to focus on selected parts of CIAT's activities and to lay the groundwork for capacity building regarding IP/TP management within CIAT. The Auditors, in cooperation with CIAT Management, agreed upon a selection of programs to be reviewed. The plan was to Audit the selected portions of CIAT's activities and to provide a pragmatic basis for CIAT's decisions regarding future policy and strategy changes.

The Auditors reviewed three projects in depth, prepared a Draft Laboratory Notebook Policy, and worked with senior management and staff on various aspects of current and ongoing negotiations. The Audited projects cut across CIAT's three goal-obtaining steps and therefore are believed to give an accurate view of PP rights management issues today. It should be noted that the Audit was not intended to be a comprehensive overview of all of CIAT's research and product development activities.

Throughout, it has been apparent to the Auditors that CIAT, at all levels, is doing a commendable job with the unnerving task of functioning under the new rules that are coming into play. Staff members, whether in support areas, management functions or in research were generally well informed and universally concerned to learn more about PP rights management. Throughout the organization there was a general spirit of willingness to "learn the new rules" in order to continue to move CIAT toward its goal and in more efficient ways.

This section will provide a synthesis of the specific recommendations presented which were distilled from the project analysis (Section 2). The recommendations are discussed in three groups related to the three goal-directed steps from the perspective of management implementation. Note that recommendations 10 and 18 to 24 are not discussed in this section since they are specific recommendations related to the FloraMap™ project.

3.2.1 Initial Step: Access to Germplasm, Data, Information and Know-How

Four critical recommendations are related to this step, namely:

- Recommendation 6: CIAT should clearly define its needs when negotiating and entering into MTA agreements with third parties
- Recommendation 8: Review and revise CIAT's standard MTA (for accessing technologies and technical properties)
- Recommendation 12: Establish clear policies on negotiation with third parties to ensure consistency and compliance
- Recommendation 16: CIAT should establish procedures for receiving and sharing data from third parties
- Recommendation 17: CIAT should study the possible implication of selling products (such as FloraMap™ or seeds) on its tax-exempt 501 (c)(3) status

There is considerable overlap across these Audit recommendations. Certain of the recommendations impact one, two or all three of CIAT's goal-directed steps. Of paramount

importance to CIAT is the recognition that the accessing of nearly all germplasm, data, information and know-how (TP rights) is done (or should be done) under a MTA. MTAs are based in contract law, not in IP law. Therefore, as contracts, rights under MTAs are nearly universally recognized and enforced; much more so than IP rights. It is imperative that CIAT carefully considers what it wants to do with the TP which it obtains (middle step) from outside sources and how it wants to distribute such TP (either *per* se or in a modified form) to its clients (final step).

CIAT's goals must be clear to those conducting CIAT negotiations with outside entities. Such information need not be disclosed to the outside party, but CIAT must have a clear understanding internally of what it needs and wants and what it is capable of distributing and under what terms.

Recommendation 25: CIAT should institutionalize a central IP/TP management office to oversee all aspects of in-licensing and out-licensing

The responsibility of such as office would, at a minimum, include:

- oversee and lead all negotiation with third parties;
- ensure coordination within CIAT on all aspects related to IP and TP management; and
- assume responsibility for the implementation of procedures that reflect and respect the policies established by CIAT's Board of Trustees and strategies determined by CIAT's senior management.

The office would also need to be involved and play a critical role in the formulation of draft policies and strategies.

3.2.2 *Middle Step: In-House Research and Development*

Seven critical recommendations are related to this step, namely CIAT should consider:

- Recommendation 2: instituting a laboratory notebook protocol
- Recommendation 3: setting-up of an agreement management database and related management practices concerning the release of germplasm
- Recommendation 4: establishing internal capacity to prepare the required documentation for Freedom-To-Operate reviews
- Recommendation 5: developing agreement management procedures
- Recommendation 11: monitoring and documenting the source of all germplasm used in all breeding programs
- Recommendation 14: instituting a coordinated policy for germplasm movement between CIAT's GRU and other CIAT units
- Recommendation 15: establishing procedures for internally sharing essential research data across various CIAT laboratories

The above recommendations relate to all three management steps of CIAT's work, reflected in recommendation 26 below.

Recommendation 26: CIAT should establish formal internal procedures for the handling of all aspects related to IP/TP management

These should, at a minimum, encompass:

- internal management of data sharing and internal technology transfer (germplasm, TP, etc.);
- internal management of agreements; and
- procedures to ensure the protection of confidentiality and the documentation necessary for the future protection of CIAT's own inventions.

There are different ways this could be implemented and will be discussed in more detail in Section 3.3 below.

Recommendation 27: CIAT should offer IP/TP management training to its staff

Training related to IP/TP management for CIAT staff and management at various levels is a critical prerequisite for the smooth implementation of recommendations 25 and 26.

3.2.3 Final Step: Technology Transfer to CIAT's Clients

The final set of recommendations from the analyzed projects (Section 2) relate to recommendation 25 regarding CIAT's need to institutionalize a central IP/TP management office to oversee all aspects of in-licensing and out-licensing. For example:

- Recommendation 6: CIAT should clearly define its needs when negotiating and entering into MTA agreements with outside parties
- Recommendation 8: Review and revise CIAT's standard MTA
- Recommendation 12: Establish clear policies on negotiation with outside parties to ensure consistency and compliance

should all be assumed by such a central office in connection with recommendation 26 above.

The final set of recommendations is:

- Recommendation 7: Consider the establishment of an Office of General Counsel
- Recommendation 9: CIAT should designate a person responsible for monitoring developments under the CBD and FAO regarding FAO-designations
- Recommendation 13: Develop a strategic response plan should contract violations be alleged

These are related to actions which the Director General or his designate may consider to coordinate.

3.3 The Audit: Policy, Management and Procedural Implications

There are a number of areas where harmonizing CIAT internal policies with changing PP rights management realities need to be noted. These include Section 3.2 above which presented and discussed the specific recommendations stemming from the in-depth analysis of the three projects. From these, the Auditors derived several more generic recommendations related to IP/TP management at CIAT. These will allow the Center to establish effective management procedures and should be accompanied by a review of CIAT's IP policies and the development of corresponding implementation strategies. The sub-sections below discuss seven key areas in more detail, also addressing the possible costs involved.

Recommendation 28: **Following CIAT's analysis of the Audit, the Center should conduct a comprehensive review of all of its policies related to IP to ensure harmonization and consistency.**

Recognizing that CIAT's IP policies have been developed partly based on the Center's needs on an on-going basis and partly based on external factors, CIAT may wish to review and harmonize all its policies. This would provide different levels of management with clearer directions which are essential to implement effective and consistent strategies and management procedures.

3.3.1 Germplasm Management

Recommendation 29: **CIAT should review its policies and procedures related to the use and transfer of germplasm, and to the management of information derived thereof**

1. Record and report the receipt and distribution of all CIAT housed germplasm; developing and utilizing an adequate Germplasm Distribution Database.
2. Assure that terms governing the conditions and use of all germplasm are clearly noted to the recipient (either within CIAT or outside CIAT) at time of distribution.
3. Clarify what is required for germplasm to move from being Designated Germplasm to Non-Designated Germplasm.
4. Clarify the status of Designated Germplasm progeny.
5. Design a means for assessing whether or not all CIAT researchers follow the prescribed protocols.

Initiating harmonizing changes in the first two of these areas may be only a matter of redefining or expanding functions that are already in place. Therefore, the cost for this may be nearly

negligible. But not to provide this is to open CIAT to using germplasm in ways that are not congruent with agreements that are in place.

Points three and four are matters that is being discussed in larger international fora and as yet is not clearly determined. Until such time as clear determinations are made, CIAT is well advised to tread carefully in this area until more widely accepted definitions are developed and accepted by the CGIAR system. Both points have significant political impact. Neither can be safely ignored, particularly if CIAT wishes to obtain statutory protection on CIAT-made discoveries.

The final point *Design a means for assessing whether or not all CIAT researchers follow the prescribed protocols* is a recurring concern the Auditors uncovered through inadequate documentation and discussion with various CIAT personnel. This implies widespread appreciation of the problem within CIAT and a possible statement of willingness to see the matter promptly resolved.

It would appear that none of these points for harmonization will require the expenditure of large amounts of CIAT resources but, particularly the final three points, may have different but large political ramifications and strategic implications.

3.3.2 Central Management

Recommendation 30: CIAT should formalize its various procedures affecting IP/TP management, ranging from confidentiality to staff and client training

1. A single source (for CIAT or for each major program) for all information dissemination to the public, scientific press, interviews, etc.
2. On-going, scheduled, staff member training to clarify CIAT's changing rights and obligations under agreements with Non-CIAT partners.
3. Uniformly applied policy for field visitors, posters, meetings, guests, visiting scientists, visitors, etc.
4. Uniform, confidential, "declaration of invention" process.
5. Initiation of a CIAT-wide policy on laboratory notebook usage and archiving.
6. Access to patent databases and related search engines.
7. Ready access to experienced negotiation services, patent counsel and general counsel services.
8. Provision of IP/TP rights management capacity building among CIAT clients.

Initiating harmonizing changes in the first two of these areas may be only a matter of redefining or expanding functions that are already in place, with a slight expansion of staff training. Therefore, the cost for this could be near negligible.

Harmonizing of the third through fifth areas with sound PP rights management practices can be readily instituted at near negligible cost except for internal and external political overtones.

CIAT management has proactively begun instituting many such changes and clearly recognizes the value that harmonizing such policies and procedures will bring. CIAT management seems likewise to understand that not instituting these changes has potential to bring CIAT into conflict with its clients as well as its non-CIAT collaborating partners and may effectively prevent CIAT from protecting discoveries made by its researchers.

The next two points (patent databases and professional services) are critically important to PP rights management. These services tend to be quite expensive, so if these are instituted, CIAT will have to closely monitor their use for excessive resource drain. While the simplest approach to obtaining such services would be to add additional trained personnel, this is also the most resource expensive solution.

As an alternative to CIAT employing more staff members and instituting these functions for itself, it may be resource enhancing to obtain such services, on an *ad hoc* basis, from a service provider. Another alternative would be to establish (or join) a multi-party consortium where CIAT can join with one or several other CG Centers who need similar sorts of services.

Regardless of the means by which these services are obtained, the services are essential for PP rights management. With these services CIAT can proactively use PP rights management to serve its programs and objectives. Without them it will be impossible to adequately function under the changing PP rights management rules.

The final point (client capacity building, point 8) is an important step toward CIAT's overall goal. This involves, in part, the level of responsibility that CIAT chooses to take for the decisions and actions of its clients. If CIAT sees such a responsibility, then it needs to set in place the process for client capacity building. Such capacity building must also involve developing adequate capacity within CIAT clients for them to understand contracts that the client may consummate either with CIAT or with another party.

All of these issues may be more concerns of the CIAT BOT and presumably of the CGIAR as a whole than of CIAT Management alone. The questions to be asked include: "Will CIAT supply improved germplasm, either transgenic or non-transgenic, to a client country without verification of the client's Proprietary Property rights management and/or biosafety management capability?" and, "Is providing capacity building in the areas of Proprietary Property rights management and biosafety CIAT's responsibility?" and, "What responsibility, if any, does CIAT have for the behavior of its clients with regard to the client's use of CIAT improved germplasm if it contains Proprietary Property of third parties?" Providing answers to these and related questions will require varying levels of resource consumption and different levels of political issue resolution from clients as well as donors.

3.3.3 Agreements Management

Recommendation 31: CIAT should harmonize its policies and procedures, and formalize its management, of its agreements

1. Harmonization of CIAT policies and procedures with terms of non-CIAT agreements both before and after negotiations.
2. Establishment of a management database to record and report the terms of all CIAT and non-CIAT agreements and obligations contained therein.

Initiating harmonizing changes in the first of these areas may be only a matter of redefining or expanding functions that are already in place. This is more an issue of experience, time and management than financial resources. Therefore, the cost for this could be near negligible.

The second area is crucial, particularly in light of CIAT's strategy to expand its collaborations with non-CIAT entities. Its implementation is not without resource expenditure, both for the software and the establishment of such a database and for its day-to-day management and maintenance. There is also the cost of harmonizing such a database with other CIAT databases (i.e. germplasm database, Proprietary Property database, etc.). However, not having some ready means of agreement management leaves unanswered many questions regarding CIAT's ability to manage its own Proprietary Property rights, especially as the number of agreements and their complexity increases.

3.3.4 Biotech Component Management

Recommendation 32: CIAT should ensure that certain terms used in agreements are clearly defined and that the implications of standard definitions are properly understood

1. Distinguishing between "research only" and "commercial" licenses.
2. Harmonizing access to external biotechnology component sources.
3. Clarifying to all, inside and outside CIAT, whether CIAT's release of transgenic, improved germplasm constitutes commercial activity under statutory protection laws.

The distinction between research and commercial licenses was relatively unimportant to CIAT when the principal mode for reaching its goal was traditional plant breeding without the use or incorporation of PP elements. The importance of understanding the distinctions changed dramatically with the expansion of plant patenting and the seed industry introducing "bag tag" (licenses that a seed purchaser accepts when the bag is opened in the same way that a software purchaser accepts certain restrictions *via* a "shrink wrap" license) language.

Nowhere is this more pronounced than with accessing biotechnology components. Misunderstanding the limitations of a research-only license may bring into question the ability to seek statutory protection on CIAT-made discoveries. Such misunderstanding may advance the

development of improved germplasm products that will be found to be in violation of the terms of a material transfer agreement or other contract that CIAT has signed. For CIAT to manage PP rights these distinctions must be recognized, understood, acknowledged, and enforced.

Not only is functioning within the limits of such agreements ethically required (accepting that it is unethical to enter into an agreement knowing in advance that one does not want to or cannot respect the terms of the agreement), it is a practical consideration to prevent possible lawsuits. Ethical functioning is essential to CIAT's relationships with non-CIAT collaborators, as a model to its clients, and as a requirement from its donors. Further, because some plants or plant products that result from CIAT's improved, transgenic germplasm will reasonably enter the stream of international trade, CIAT clients need to be readily aware of PP rights issues and ramifications to their produce.

3.3.5 Biotechnology Product Management

Recommendation 33:	**CIAT must consider the implications of various options related to Freedom-To-Operate and should establish and communicate its position and mode of operation**

1. Determine at what level CIAT should inform its clients on FTO information related to its transgenic products.
2. Establish internal capacity to contribute to FTO reviews.

Freedom-to-Operate: What is it?

A FTO opinion is a risk management opinion. It is written by an attorney for the purpose of guiding an organization through or around perceived risks. These risks include aspects related to patents on products and processes that may influence an organization's freedom to distribute and use the materials derived therefrom. Sometimes a FTO opinion may be broadened to cover biosafety and other regulatory aspects and obligations. FTO opinions will vary on a country-by-country basis because most statutory protection is founded in national law. Similarly, FTO opinions are dynamic because patent status is dynamic. So FTO opinions must be regularly reviewed and updated.

An FTO opinion is just that; *an opinion.* It is not a definitive answer but only a patent attorney's opinion that if a dispute arises, the organization's behavior can be justified. Given currently popular crop improvement strategies, virtually no release of germplasm is without some degree of risk. As transgenic strategies begin to dominate crop improvement practices, both the risks and rewards of releasing improved germplasm can be expected to rise.

Managing Freedom-to-Operate:

As noted above, a FTO has to be conducted for a specific country in which a product is to be released. For CIAT, however, since its clients are diverse, the institute may wish to implement the following strategy:

- a certification of well known, easily-obtained Proprietary Property rights;
- it may come with CIAT's offer to help the recipient resolve FTO issues.

Alternately, CIAT may wish to apply different degrees of FTO to different products, different components, on a client-by-client basis, or on a product-by-product basis, or based on other factors. Each option CIAT chooses has different consequences and it is imperative that CIAT considers the various options and implications. What is critical is that its clients know what information they are being given and what their own options are.

Essentially, CIAT has three options:

1. ignore FTO
2. conduct or commission a selective or preliminary (or broad-brush) FTO
3. conduct or commission a comprehensive FTO on a global basis and/or tailor made for each country of release

The three different options have different characteristics. Option 2 and 3 have the following:

Option 3. Consequences of Applying Comprehensive FTO

1. Highest level of PP rights to the CIAT client.
2. Requires significant resource commitment (internal and through outsourcing).
3. Some funding sources may find a Comprehensive FTO inappropriate.
4. Induce changes to CIAT's organizational structure requiring at a minimum:
   - an Office of General Counsel;
   - an Office of Intellectual Property and Technology Transfer Management;
   - renewed emphasis on public information;
   - access to specialized databases and para-legal and legal services.
5. Take measures to ensure that clients do not become dependent on CIAT's provision of FTO.
6. Could be provided as a cost-effective service (since CIAT would perform/outsource the FTO for the range of NARS) to clients.
7. Preclude any Proprietary Property rights concerns *vis-à-vis* the private sector.
8. Draw resources away from serving the poorer of the poor unless additional resources can be leveraged through the process or unless improved product development becomes significantly more effective.

Option 2: Consequences of Applying Selective FTO

1. Delegate much PP rights management to client countries. (It should be recognized, however, that the majority of NARS do not, at this stage and for the foreseeable future, have the capacity and resources to have a Comprehensive FTO executed or commissioned).

2. Limited use of CIAT resources.
3. Constitutes a major challenge to non-CIAT research relationships once the products are ready to be transferred to and deployed by NARS.
4. Collaboration with the private sector might be more sporadic.

Possible Effects on CIAT with selective use of Comprehensive and Partial FTOs

For CIAT, or more broadly for the client and donor community, either approach would require resolution of the issues listed below. It should be noted that whereas for the Comprehensive FTO approach, certain offices would need to be established by CIAT, for the Selective FTO approach, CIAT would still need a subset of the same activities but to a lesser degree. Such a blend of Comprehensive FTO and Selective FTO, on a project-by-project basis, a country-by-country basis, a component-by-component basis, or on some other basis, may be a feasible interim approach and may concurrently reduce some of CIAT's resource requirements. At the same time, such a variable application may increase CIAT's administrative requirements.

1. Office or Service of General Counsel for CIAT (internal or external) whose duties would be to offer legal advice regarding:
   - negotiations with non-CIAT entities;
   - harmonization of CIAT-non-CIAT agreements with CIAT policies and procedures;
   - introduction of internal protocols for release and recording of all classes of germplasm and related information held by CIAT;
   - receive all confidential statements of invention from CIAT researchers;
   - file and direct the statutory (patent, copyright, PVP, other) protection of CIAT discoveries;
   - develop strategies toward enforcement of CIAT statutory protection rights;
   - respond to all challenges to CIAT regarding FTO rights matters;
   - direct CIAT litigation that may arise from enforcement of statutory protection rights;
   - other as required.

2. Office or Service of Proprietary Property Management whose duties would be to:
   - serve as a single point of contact for all CIAT product releases through licensing or otherwise;
   - serve as a single point of contact for the receipt of all proprietary material and information that is received by CIAT researchers;
   - draft, with advice from the Office of General Counsel, all Proprietary Property rights agreements;
   - negotiate, with advice of the Office of General Counsel, all agreements with Non-CIAT entities;
   - compile, manage, and report to CIAT management regarding CIAT's on-going Proprietary Property duties and responsibilities under the several agreements;
   - other as required.

3. Office or Service of Information whose duties would be to:
   - serve as a single point of contact for all CIAT press releases and other public statements including staff member publications, meeting attendance, and poster presentations;
   - implement and maintain a laboratory notebook policy across all CIAT locations;
   - manage guest visits, short-term staff appointments, etc.;
   - provide staff member training regarding those new policies and procedures that are required to harmonize obligations that CIAT may have obtained through agreement with a Non-CIAT entity;
   - coordinate the responses to criticism by the public and/or a variety of NGOs;
   - coordinate the responses and manage the interface with clients and donors due to the changed relationships with CIAT clients resulting from giving different treatment to different client nations;
   - other as required.

4. Introduction of adequate databases to report and coordinate CIAT's accrued Proprietary Property rights and obligations. This would include databases relating to:
   - CIAT maintained germplasm, regardless of source;
   - agreements with Non-CIAT entities;
   - duties and obligations accruing from CIAT-Non-CIAT agreements;
   - patent and related scientific publications;
   - other as needed.

3.3.6 Electronic Data Management

See Recommendation 16: CIAT should establish procedures for receiving and sharing data from non-CIAT parties

The PP rights for electronic information is very much in flux. They are more often regulated by a country's laws than by international treaty, and they may be sporadically enforced, particularly in developing countries. However, changes by way of both country laws and international treaties are fast being set in place.

Many commonly practiced activities that may be violations of law (at least in some countries) are coming under increased scrutiny. Harmonization of CIAT policies and procedures with PP rights management regarding electronic information acquisition and dissemination can be instituted for the cost of obtaining appropriate legal opinions and the re-writing of certain CIAT policies. To not re-write CIAT's policies and procedures could cost CIAT much credibility in the eyes of donors and non-CIAT collaborators. Finally, disregard for PP rights enforcement at CIAT sends clients an uneven PP rights management capacity message.

4. CONCLUSIONS

Harmonization of CIAT's policies and procedures with systematic and predictable PP rights management practices is not without cost, either financial or political. However, failure to do so will, in the long term, adversely affect CIAT's relationship with its staff, its clients, its donors and non-CIAT collaborators. This CIAT can not afford to do. On the other hand, instituting these steps toward harmonization will put CIAT on the proactive path that it has historically taken in its leadership role within the international research community.

Re-writing policies is relatively inexpensive. Likewise, for enforcement of the revised policies. However, having a clear understanding of PP rights management is essential for strong relationships with all classes of non-CIAT entities. Strong relationships flow from honesty and consistency. Where agreements with a non-CIAT party were entered that do not consistently reflect CIAT policies and procedures, two choices exist:

1. Change the agreement, or
2. Change the policies and procedures.

Re-negotiation of agreements prior to a dispute is typically preferable to waiting until a potential misunderstanding has grown to unmanageable proportions.

This Audit, of a limited number of CIAT projects, should be taken only as a starting point for continuing reviews of IP/TP issues by CIAT staff and management. As the Audit report is integrated into CIAT's on-going activities, CIAT managers and staff members will develop the capacity to deal with the current recommended changes as well as proactively handle future IP/TP issues as they arise.

As with the game of hockey, there are times when one or the other team seeks clarification of the rules of the game. Clarification and interpretation of the rules allows the activity to proceed toward the goal.

CIAT's goal is not now and has never been in doubt. Effective IP/TP management has the potential to make its endeavors more effective. In a certain way, CIAT has no option but to deal with the IP issues since the rules have changed. The challenge for CIAT now is to continue on its path and reinforce its measures and activities to change, to better understand the new rules, and to capitalize on them for the benefit of the resource poor farmers it serves.

LIST OF APPENDICES (under separate cover)

Appendix 1. Patent Cover Pages, Rice Hoja blanca virus Product Clearance Spreadsheet

Appendix 2. Plasmid construct pVR3, used by CIAT in rice transformation

Appendix 3. Plasmid Map, pRT100 (pRT101)

Appendix 4. Plasmid Map, pGSFR761A

Appendix 5. Plasmid Map, pBS +/- phagemid vector

Appendix 6. Biolistic® PDS-1000/He Purchase Agreement

Appendix 7. March 11, 1993 Letter from William Roca to Bio-Rad, indicating how PDS-1000/He system will be used at CIAT.

Appendix 8. CIAT Intellectual Property Rights Policy

Appendix 9. CIAT Material Transfer Agreement

Appendix 10. Agreement Between Semillas Papalotla, S.A. de C.V. and The Centro Internacional de Agricultura Tropical on Exclusive rights for the commercial distribution and registration of Brachiaria hybrid CIAT 36061

Appendix 11. Agreement Between the "Centro Internacional de Agricultura Tropical" (CIAT) and the Food and Agriculture Organization of the United Nations (FAO) Placing Collections of Plant Germplasm Under the Auspices of FAO

Appendix 12. Data input for SAMMDATA

Appendix 13. Digital Chart of the World (DCW) for use with ARC/INFO® software License Agreement & Customer Service Information

Appendix 14. MapObjects LT Product Description

Appendix 15. ESRI MapObjects™ License Terms

Appendix 16. ESRI Copyright Permission and Release Form

Appendix 17. CIAT-Trademarks Etc., FloraMap Correspondence

Appendix 18. FloraMap Word Mark Filing, U.S. Trademark Electronic Search System (TESS)