CHAPTER 16.5

Bioprospecting Arrangements: Cooperation between the North and the South

DJAJA DJENDOEL SOEJARTO, *College of Pharmacy, University of Illinois at Chicago, U.S.A.*
C. GYLLENHAAL, *University of Illinois at Chicago, Chicago, U.S.A.*
JILL A. TARZIAN SORENSEN, *Global Health Initiatives, Johns Hopkins University, U.S.A.*
H.H.S. FONG, *University of Illinois at Chicago, Chicago, U.S.A.*
L.T. XUAN, *National Center for Science and Technology, Hanoi, Vietnam*
L.T. BINH, *National Center for Science and Technology, Hanoi, Vietnam*
N.T. HIEP, *National Center for Science and Technology, Hanoi, Vietnam*
N.V. HUNG, *National Center for Science and Technology, Hanoi, Vietnam*
B.M. VU, *Supporting Center for Community Economic Development, Hanoi, Vietnam*
T.Q. BICH, *Cuc Phuong National Park, Ninh Binh, Vietnam*
B.H. SOUTHAVONG, *Traditional Medicine Research Center, Vientiane, Lao People's Democratic Republic*
K. SYDARA, *Traditional Medicine Research Center, Vientiane, Lao People's Democratic Republic*
J.M. PEZZUTO, *University of Hawaii at Hilo, U.S.A.*
M.C. RILEY, *College of Pharmacy, University of Illinois at Chicago, U.S.A.*

ABSTRACT

The ICBG (International Cooperative Biodiversity Groups) program, through which institutions located in biotechnology-rich countries in the North collaborate with institutions located in the biodiversity-rich countries in the South (with the support of an industrial partner) to discover and develop natural-product drugs, is an experiment in the design of bioprospecting efforts. This chapter describes the general aims and organization of the ICBGs and describes in great detail the agreements that governed the University of Illinois at Chicago-Vietnam-Laos ICBG. The chapter includes material concerning IP (intellectual property) rights issues, informed consent, various forms of benefit sharing (including the sharing of short- and long-term, namely, royalty, benefits), capacity building, and community reciprocity. It offers a model for other such agreements.

1. INTRODUCTION

The term *bioprospecting* or *biodiversity prospecting* has been defined as "*the exploration of biodiversity for commercially valuable genetic and biochemical resources*,"[1] or "*the search for wild species, genes, and their products with actual or potential use to humans*,"[2] or the search for commercially valuable biochemical and genetic resources in plants, animals, and microorganisms.

One model of a biodiversity prospecting effort is a program called ICBG (International Cooperative Biodiversity Groups). Based in the United States, ICBG falls under the auspices of the Fogarty International Center (FIC) of the United States National Institutes of Health (NIH). It also collaborates with the National Science Foundation (NSF) and the U.S. Department of Agriculture (USDA).[3] A five-year cycle program, it went into operation in 1993 in response to a request for applications issued by FIC in 1992.[4] The ICBG second cycle began on 1 October, 1998, as a result of new and recompeting proposals in response to a request for applications issued by FIC in 1997.[5] On 17 October 2002, a request for applications for a 2003–2008 ICBG cycle recompetition was again issued.[6]

2. THE ICBG PROGRAM

International Cooperative Biodiversity Groups, or ICBGs, address the interdependent issues of drug discovery, biodiversity conservation, and sustainable economic growth. They are founded in the belief that efforts to examine the medicinal

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potential of the earth's plants, animals, and microorganisms are urgently needed, and that continuing habitat destruction and ever-diminishing biodiversity will make it increasingly difficult to do so in the future. If bioprospecting directly benefits local communities and source country organizations, ICBGs believe that they will have strong incentives to preserve and support sustainable use of the environment.[7]

As a result of the 1992 and 1997 ICBG award competitions, eight ICBGs were established.[8] Each ICBG has as its administrative base a U.S.-based institution that is paired with other organizations (governmental and nongovernmental, including industrial/pharmaceutical) that are located both inside and outside the United States; one of these organizations is a host institution in one or more developing, biodiversity-rich countries, usually in the South. The personnel, organizational structure, specific aims, and methods of operation of each of these ICBGs have been fully described elsewhere.[9]

3. THE NORTH/SOUTH ICBG BIOPROSPECTING ARRANGEMENT

ICBG proposals must address access and benefit-sharing (ABS).[10] ABS is based on contractual agreements that take into account:

1. **The benefits that may be derived from bioprospecting.** These may include royalties from the sales of drugs developed from bioprospecting, advance payments (access fees or payments for samples when a commercial partner is involved), capacity building (equipment, training, infrastructure), and focus on the priority areas in the country(ies) of the host institution(s), such as priority diseases or collections and identification in geographic areas or biological groups that are high priorities for conservation needs.
2. **The recipients of the benefits.** These may include individuals and communities, government institutions (including national parks, forest services, national herbaria), and nongovernmental institutions (including universities, conservation and development service organizations, and private companies). Whether or not useful ethnomedical knowledge comes from the bioprospecting efforts, communities must receive both short- and long-term benefits for collaborating in the research process.
3. **The negotiation process.** Negotiators should consider the following elements:
   - *Informed consent*, from informal disclosure of the potential uses of their knowledge offered by individuals or communities, to formal documentation in the form of project descriptions and related materials
   - *Consensus building* among communities and government and nongovernmental organizations
   - Independent legal advice for all consortium members
4. **The structure of the agreement between the recipients.** ICBG models include the *one-contract model*, the contract wheel, the dual-contract model, and the wheel-triangle model.[11] All of these agreements include research and benefit-sharing terms, intellectual property (IP) rights, material transfer, confidentiality, and other terms. Often, specific agreements may address components of the above, including material transfer agreements (MTAs), know-how licenses, and so on.

4. THE UNIVERSITY OF ILLINOIS AT CHICAGO-VIETNAM-LAOS ICBG

4.1 *Background*

The members of the UIC ICBG Consortium were the University of Illinois at Chicago (UIC); the Vietnamese National Center for Science and Technology (NCST), based in Hanoi, Vietnam; Cuc Phuong National Park (CPNP), in Ninh Binh, Vietnam; the Traditional Medicine Research Center (TMRC), based in Vientiane, Laos, (formerly named the Research Institute for Medicinal Plants [RIMP]); and Glaxo Wellcome Research and Development (GW), based in Greenford, U.K. (today known as GlaxoSmithKline [GSK]).

The grant award (made on 29 September 1998) represented a cooperative agreement between the U.S. Government and UIC. The letter of award (Terms and Conditions of Award) indicated that the U.S. government agreed to fund the work (via the FIC) of the UIC-based ICBG, so long as certain criteria were met: the principles of ABS were fulfilled, the progress of the project was satisfactory, and funds were available.[12]

The general background of the ICBG (the events that led to the writing of the proposal, the selection of partner institutions, and the submission of a Letter of Intent to submit a proposal to the FIC), as well it's the structure of the ICBG (personnel, organization, research plan, and policies toward IP rights and informed consent) have been described in an earlier paper.[13]

4.2 *The aims of the consortium*

The specific aims of the UIC-Vietnam-Laos ICBG were:

- The discovery of biopharmaceuticals in the plants of Vietnam and Laos and the development of drugs to treat cancer, AIDS, malaria, tuberculosis, pain, and diseases that affect the central nervous system (particularly Alzheimer's disease)
- Creating a biodiversity inventory and conserving biodiversity, with a specific focus on plants of Cuc Phuong National Park and medicinal plants of Laos
- Aiding economic development in cooperating communities
- Capacity building among the collaborating institutions in the host countries

4.3 *Negotiations among consortium members*

After the Letter of Intent was submitted to the FIC on 3 October 1997, discussions were held between the principal investigator and the director of UIC's IPO (Intellectual Property Office). An important element of discussions was the principle stated in the so-called Manila Accord (at the 1990 Regional Workshop for the Chemistry of Natural Products in Southeast Asia), which states that at least 51% of the income generated from the commercialization of a drug derived from a plant collected in a particular country should go to the institution located in the plant's country of origin. The eventual outcome of these discussions was a Memorandum of Agreement (MOA) that bound the five members of the UIC ICBG. The ICBG proposal and the draft MOA (which had been accepted by member institutions but not signed) were sent to the FIC on 20 January 1998.

The new ICBG, Studies on Biodiversity of Vietnam and Laos: The UIC-based ICBG Program, was created on 1 October 1998. Its bioprospecting program was not fully functional until nine months later, when the MOA was signed by all parties on 28 June 1999. In the negotiation process, the principal investigator of this ICBG advised NCST, CPNP, and TMRC to consult attorneys regarding the draft MOA.[20]

4.4 *The Memorandum of Agreement*

The MOA consists of 15 pages of text plus 5 Addenda (which total 5 pages). Addenda I and II are included at the end of this chapter (Figures 1 and 2) and are further discussed below. It should be noted that the natural product program at GSK was phased out in 2000 as a result of the merging of GW and Smith Kline Beecham, so GW/GSK withdrew from the consortium in November of 2001.

4.4.1 *The MOA structure*

The University of Illinois at Chicago, which is bound in a contractual agreement with the U.S. government, is the administrative seat of the consortium. The transfer of funds (grants, not IP rights or benefit-sharing agreements) from UIC to the other member institutions (except Glaxo) was outlined in separate subcontract agreements. Glaxo was not a recipient of ICBG funds and did not provide any funding to the consortium; it did, however, agree to contribute to capacity building of scientists and institutions in Vietnam and Laos.

4.4.2 *Clauses of the MOA*

Part I of the MOA defines the consortium members' Scope of Cooperation. Part II defines the General Areas of Cooperation of the consortium members, including the exchange of faculty members or scientific personnel, joint research activities, joint participation in seminars

and scientific meetings, the exchange of academic and research materials and other information, and the participation in special short-term academic programs. Part III describes the details of the joint research activities and consists of five sections (III-A/Precedents, III-B/Purpose, III-C/Objectives, III-D/Responsibilities, and III-E/Finance and Services).

- *III-A/Precedents* contains clauses that describe the considerations that led to the cooperation, such as the previous track record of collaboration between UIC and the member organizations, the proposal writing, the funding award, the key personnel and organizational structure/component roles, and a reference to the terms and conditions of the ICBG award.
- *III-B/Purpose* defines the purpose of the cooperation: to discover and develop new medicines, to conserve and sustainably use the flora of the Cuc Phuong National Park in Vietnam and the medicinal flora of Laos, and to increase development in both cooperating communities and in the ICBG host institutions.
- *III-C/Objectives* spells out the specific aims of the consortium, including its approaches to plant selection, disease targets, the inventory of the seed plants of CPNP, biomass production of biologically active and promising species, capacity building, conservation education, economic improvement of local communities, in the CPNP area in Vietnam, and medicinal-plant inventory and databasing (and community reciprocity) in Laos, as well as human-resource development and infrastructure strengthening of the ICBG host institutions in Vietnam and Laos.
- *III-D/Responsibilities* spells out the responsibilities of each member organization and their joint responsibilities.
  - III-D-1 defines the responsibilities of UIC (23 clauses).
  - III-D-2 defines the responsibilities of NCST, IBT, ICH and IEBR (14 clauses).
  - III-D-3 defines the responsibilities of CPNP (12 clauses).
  - III-D-4 defines the responsibilities of RIMP/TMRC (11 clauses).
  - III-D-5 defines the responsibilities of Glaxo/GW (ten clauses).
  - III-D-6 defines the joint responsibilities of the member institutions and the industrial partner (eight clauses). It includes the time period the MOA is in force, conditions for withdrawal of any of the member organizations, amount of samples at initial collection for screening and recollection for isolation and structure determination, conditions for exchange of personnel as part of capacity building, the requirements for technical reports, how the materials and data may be used in the event the agreement is terminated, the limitations on the collaborative use of genetic materials, requirements for acknowledging the grant in publications, and the requirement that international arbitration must be sought in the event of disputes.
- III-E specifies the source of funding as the FIC/NIH (ICBG Grant 1UO1-TW01015-01).

Part IV defines the period of validity of the MOA; the conditions for termination, extension, and amendment of the MOA; and the number of copies of the MOA that must be signed by members of the consortium.

The signature page states that the five addenda to the text of the MOA will become binding upon the signing of the legal representatives whose names are affixed therein. These include the chancellor and two representatives of the board of trustees (for UIC), the director of the Institute of Biotechnology and an ICBG-NCST liaison (for NCST, representing IBT, ICH, and IEBR), director and vice director of Cuc Phuong National Park, director and deputy director of TMRC, and director for scientific research of GW.

- **Addendum I** (Figure 1) describes a long-term benefit-sharing scheme that will go into effect in the event that discovery of a biopharmaceutical is made by UIC (in cooperation with ICH) and that Glaxo develops and commercializes the drug. In this scheme, the royalty stream is distributed among the organization members of the Vietnam-Laos ICBG (excluding Glaxo, which waived its share of any royalties) and the communities in the ICBG host countries.
- **Addendum II** (Figure 2) presents a long-term benefit-sharing scheme to go into effect in the event that Glaxo discovers, develops, and commercializes the drug. As in Addendum I, in this second scheme, the royalties are distributed among the member organizations (excluding Glaxo) and the communities in the ICBG host countries.
- **Addendum III** grants rights to GW in the event of the licensing of discoveries made at UIC-ICH under the framework of the ICBG and GW's rights of first refusal.
- **Addendum IV** defines the milestone payments that GW will make in the event a drug is discovered at UIC. The amount of payment is determined by the following variables: the site of the screen (UIC versus GW), the selection of compound for clinical trial, entry to Phase II and Phase III clinical trials, and approval of NDA (New Drug Application).
- **Addendum V** defines milestone and royalty payments for any drug developed and commercialized by GW. The payments are determined by the patent rights on, and the chemical structure of, the GW development compound, as well as by the target activity (in other words, whether or not the target is one of those in which ICBG is interested). Milestone and royalty payments will be made on new drugs that are derivatives of natural compounds discovered in collected plants, as well as on the natural compounds themselves.

4.5. *IP rights issues*

In the event of a relevant UIC discovery, the IPO of UIC-PCRPS will determine the ownership of any resulting IP with the assistance of all members of the Group. The named inventors may consist of individuals from any or all of the consortium members. The question of ownership shall be determined in accordance with the applicable laws of the country in which the invention or discovery is made. With the assistance of all members of the consortium, the UIC IPO will obtain patent protection for the invention or discovery and/or seek such other IP protection, as UIC deems appropriate. UIC IPO will be responsible for the management and licensing of the invention or discovery in accordance with the terms of the agreement.

In the event that an invention or discovery is made at GW based on plants that were collected or acquired within the ICBG framework, GW will determine the ownership of any resulting intellectual property with the assistance of all members of the consortium. The named inventors may consist of individuals from any or all of the consortium members. The question of ownership shall be determined in accordance with the applicable law of the country in which any invention or discovery is made. GW will obtain patent protection for such invention or discovery and/or seek such other intellectual property protection, as GW deems appropriate with the assistance of all members of the Group. GW will be responsible for the management and licensing of such protected inventions. The parties further agree that they will make available all relevant information to GW (including the country of origin of the sample and its taxonomic identity, where appropriate) so that GW will be able to register IP rights.

GW will have the rights to file for patent protection for a discovery it makes that is based on plant samples or extracts received by GW under the framework of the ICBG, but it will consult with the consortium in determining co-inventorship of the discovery. GW also agrees to notify the consortium in the event a decision is made to proceed with the development of a compound or

compounds derived from plants supplied by the ICBG.[21]

4.6 *Informed consent*

There are two provisions regarding informed consent in the Vietnam-Laos ICBG agreement: (1) informed consent in the case of collection and use of plant/genetic materials and (2) informed consent of individuals and their communities regarding the traditional medicinal use or uses of a plant.

Thus, in Vietnam, "*informed consent (collecting permits) of the Government of Vietnam, the owner of the samples (genetic materials) and derivatives thereof, will be secured before the implementation of the work proposed as described in the ICBG proposal*," and ICBG through IBT, IEBR, and CPNP "*will liaison with the Government of Vietnam in matters related to permit for the collection and export of plant samples or their extracts for use in the ICBG project*." In Laos, TMRC/RIMP will collect plant samples from various sites in Laos "*through prior informed consent of the Government of Lao PDR, the owner of the samples (genetic materials) and derivatives thereof*." Prior informed consent (collecting permits) will be secured before the implementation of the work. The governments of Vietnam and Laos are acknowledged as the owners of genetic materials and their derivatives in their respective countries.

In Vietnam, ICBG investigators "*will seek the informed consent of individuals and/or communities for the recording and use of data on the medicinal and other uses of the plants in the Cuc Phuong National Park, for the intended study as described in the ICBG proposal*." In Laos, ICBG investigators "*will seek the prior informed consent of individuals and/or the communities for the recording and use of data on the medicinal and other uses of plants of Laos, for the intended study as described in the ICBG proposal*."

4.7 *Royalty distribution*

The full scheme of royalty distribution in Addenda I and II of the MOA (Figures 1 and 2) has been presented in an earlier paper.[14] At the time of ABS negotiations, UIC channeled the net royalty stream (after deduction of out-of-pocket costs) received from an industrial partner or licensee into two equal portions. The first 50% (referred to as the "common fund") is to be distributed to the collaborating institutions, the inventors, and the UIC administration, while the other 50% is to flow back to communities in the country of origin of the genetic material of the commercialized product, through a trust fund.

The distribution of the first 50% share may happen in two different ways. In the first scenario, UIC investigators discover a drug, and a pharmaceutical company develops and commercializes the compound. In the second scenario, a drug is discovered, characterized, developed, and commercialized by a pharmaceutical company that is an ICBG industrial partner (in other words, UIC inventors do not hold IP rights).

In the first instance (UIC inventors hold IP rights) the common fund is to be distributed as follows: (1) the inventors will receive a 40% share of the 50% portion (equal to 20% of total net royalty), as an incentive for future inventions; (2) the collaborating institutions (PCRPS and counterpart institutions) will receive a 20% share of the 50% portion (equal to 10% of total net royalty) for their research contributions; and (3) the UIC administration will receive a 40% share of the 50% portion (equal to 20% of total net royalty) for their administration and legal contributions.

In the second scenario (UIC inventors do not hold IPR), the common fund is to be distributed as follows: (1) the collaborating institutions will receive a 40% share of the 50% portion (equal to 20% of the total net royalty); (2) UIC-PCRPS will receive a 20% share of the 50% common fund (equal to 10% of the total net royalty) for its research contribution; and 3) the UIC administration will receive a 40% share of the 50% common fund (equal to 20% of the total net royalty).

The full details of the UIC-based Vietnam-Laos ICBG benefit-sharing scheme are spelled out in a 2002 paper.[15] In November 2002, further discussions and analyses of the above royalty distribution schemes at UIC led to the application of the policy to joint drug-discovery efforts:

Sixty percent of the split of the net royalty would go to the collaborating institutions, while 40% would go to UIC. Despite the change of this benefit-sharing policy, the original benefit-sharing schemes set down and agreed to by the UIC ICBG consortium and embodied in the ICBG MOA remain in force to this date.[16, 22]

Funds provided by GSK at the time of its withdrawal are being used to establish two trust funds: the Nature Conservation Foundation (NCF), Vietnam, and the Laos Biodiversity Fund (LBF). The objectives of the NCF and LBF include conservation of resources, capacity building, biodiversity research, and community reciprocity.[17] These funds will serve as the conduit for the 50% of the royalties that are due to flow back to the communities in question.

4.8 *Community reciprocity*

Community reciprocity measures are implemented in the Vietnam-Laos ICBG.[18] Both the UIC and the host-country institutions have responsibility for implementing community reciprocity.

5. CONCLUSION

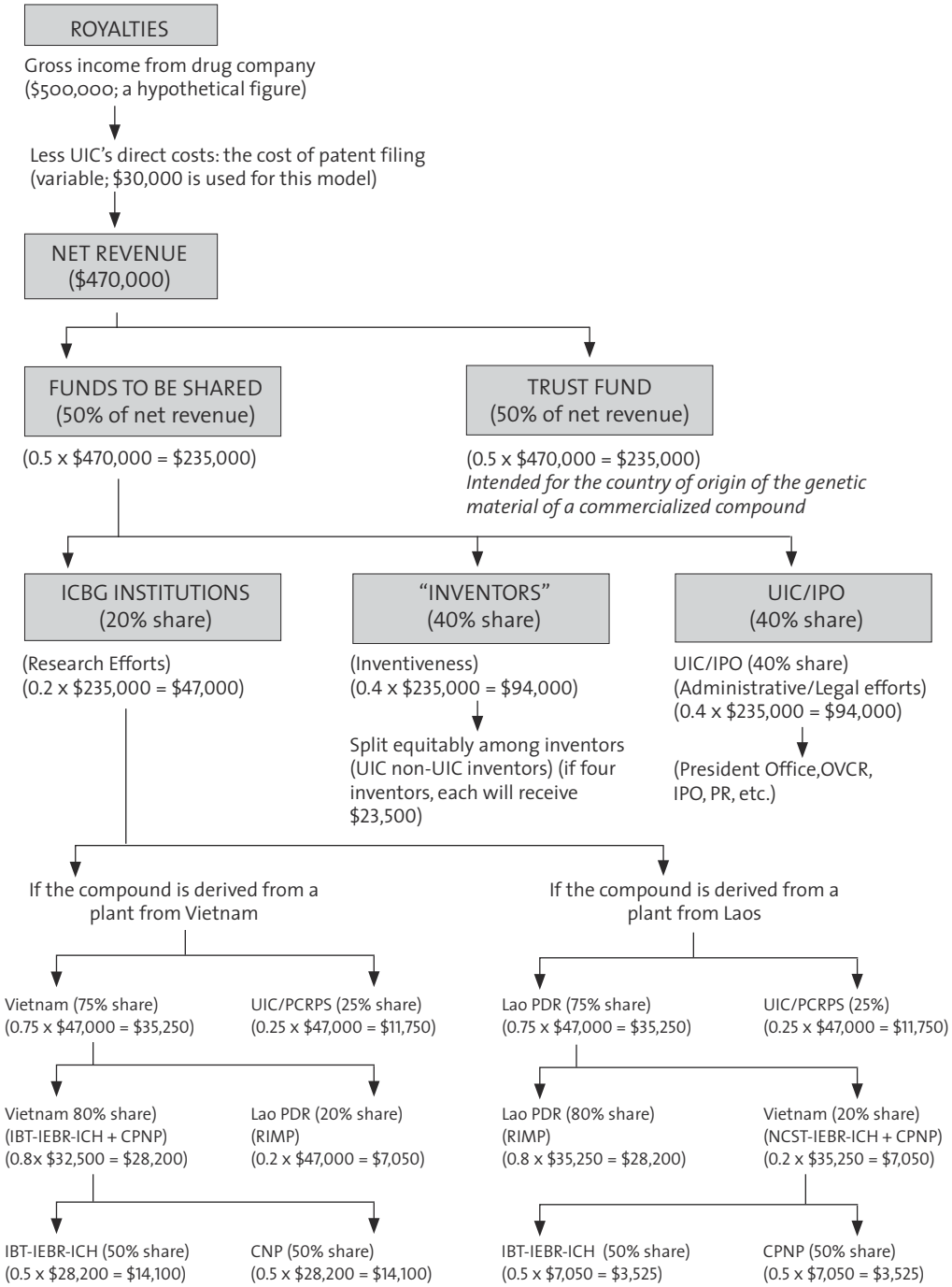
The success of an ICBG depends on the goodwill and understanding of the collaborating parties toward the achievement of a common goal, namely, the conservation of biodiversity, the discovery and development of pharmaceutically beneficial products, and the equitable sharing of the benefits that may result. In setting up the arrangement, multiple, complex requirements must be satisfied, the most important of which is the contractual agreement. Eight ICBG bioprospecting groups have so far been created, each with various models of contractual arrangement. The common features of these models, however, are their satisfactory arrangements for IP rights issues, informed consent, and benefit sharing.

The UIC-based Vietnam-Laos ICBG is one example of such a North–South collaborative arrangement. Parties to this ICBG have successfully achieved goodwill and understanding. Despite the short time it has been in operation, the accomplishments of this ICBG to date indicate that the ICBG model works.[19, 23]

Bioprospecting endeavors such as these are also unique in the way in which they involve local communities. In order to effectively carry out this sort of activity, collaboration at the local level—with poor farmers, rural villagers, many of whom have only limited education or opportunities in life—is crucial. The ICBG allows rural villagers participation in conservation, economic and development initiatives in a way that is not often seen in "macro," nation-wide efforts to promote conservation, development or new economies. (Often, villagers are told what to do or are displaced by these new initiatives.) And the ICBG also allows villagers input on a number of issues—health care delivery, education, local economics, conservation, and development—which is a natural by-product of forming the ICBG project and determining what benefits "make the most sense" to the local communities with which the ICBG works.

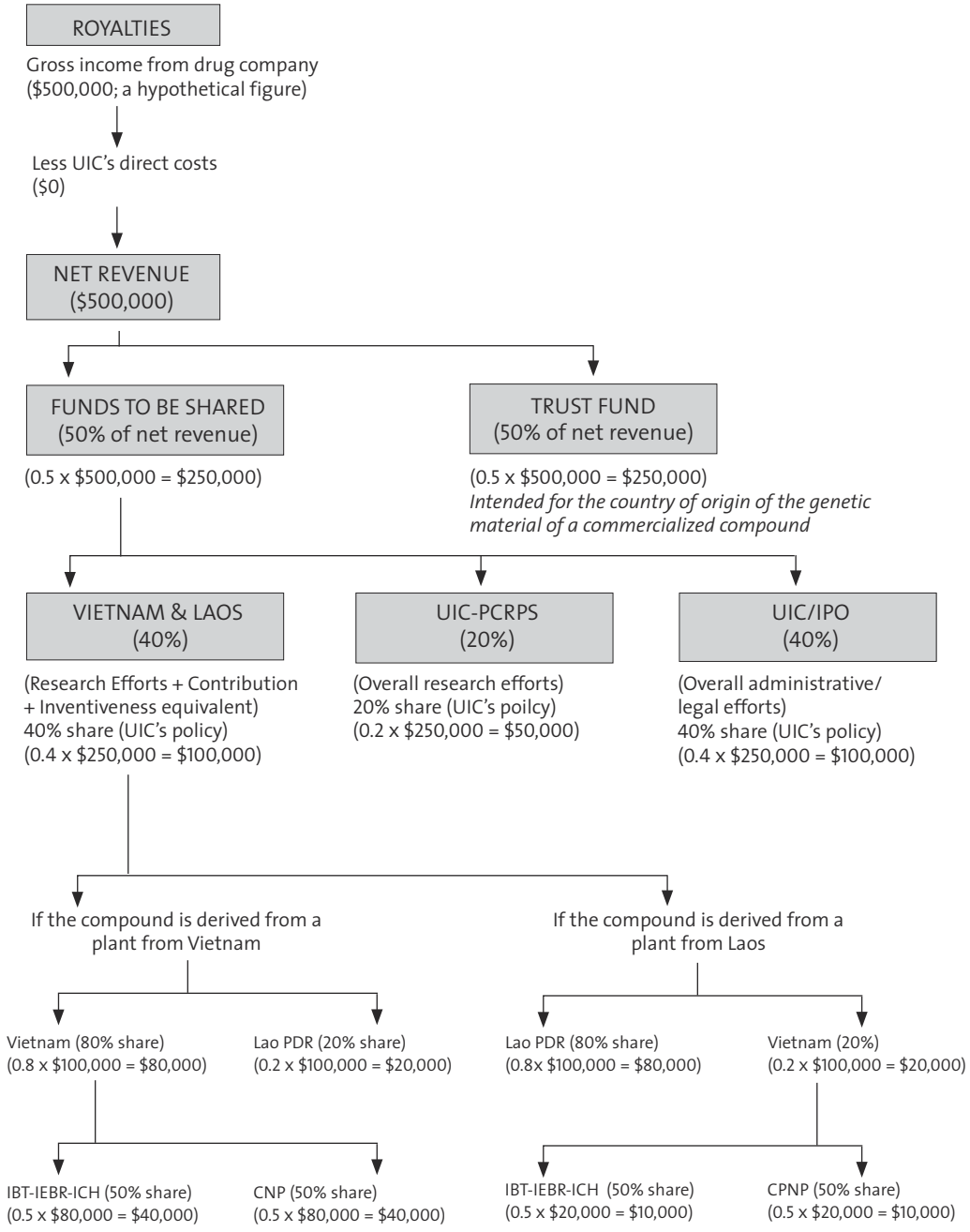
Often times in the implementation of international, national or even provincial development, conservation or economic initiatives, the peasant-farmer is left out of the dialogue entirely, or is told to change/is displaced from life-long patterns of living and working. Under these circumstances, the peasant-farmer does not have a voice, and new schemes for economy, conservation, and development are imposed upon villages from the outside rather than collaboratively developed with villagers, in accordance and consideration of the local needs of villagers in different regions of the country. Projects such as the ICBG can provide a model for how to successfully implement national policy initiatives at the "micro" level—that is, figuring out the best ways to improve health care access and delivery systems, or to implement new economic, development, and conservation initiatives that are in keeping with local village practices and rhythms of life, especially when it turns out that local villagers have their own, traditional practices that may directly or indirectly contribute to conservation, economic, and development efforts. While the governments of Vietnam and Lao PDR do attempt to take into consideration the

Figure 1: Royalties Sharing in the Event that UIC Discovers and Characterizes a Compound, and Glaxo Develops It



Note: In this scenario: a) the total amount of funds from the net royalty income that remains in the United States will be: $30,000 (direct) + $94,000 UIC share + $11,750 PCRPS share + $70,500 inventors' share = $206,250 or 41.25% of gross royalties. [If all inventors are UIC scientists, the UIC share will be: $30,000 direct costs + $94,000 UIC share + $11,750 PCRPS share + $94,000 Inventors' share = $229,750 or 45.95% of gross royalties.] and b) the total amount that will go back to the source country (Vietnam and Laos) will be: trust fund ($235,000) + ICBG institution share ($35,250) + Inventors' share (in the above scheme with one non-UIC inventor, $23,500), for a total of $293,750 or 58.75% of gross royalties. [If all inventors are UIC scientists, the share of the source country (Vietnam and Laos) will be: $235,000 trust fund + $35,250 ICBG institution share = $270,250 or 54.05% of gross royalties.

Figure 2: Royalties Sharing in the Event that GW Discovers, Characterizes, and Develops a Compound



Note: Since UIC does not file a patent in this case, no direct costs to UIC are deducted.

In this scenario, the total amount of funds from the net royalty income that remains in the United States will be: $50,000 UIC/PCRPS, share + $100,000 UIC/IPO share = $150,000 (or 30%). The total amount that will go back to the source countries (Vietnam/Laos) will be: $250,000 trust fund + $100,000 source-country share = $350,000 (70%).

needs of local villagers when implementing new policies designed to improve the quality of life in rural areas, projects such as the ICBG can act as a model for obtaining additional data on the actual living conditions of rural villagers, and how to work with and for local communities, because of the close association between the ICBG and local village authorities and councils.

Moreover, the rural villagers begin to see themselves as stakeholders interested in the outcomes of conservation, economic, development, and health care delivery efforts because of their direct participation on the process of locally implementing national policies. Instead of feeling alienated by the process of reform, rural villagers realize their direct contribution to the process itself when they are actively engaged and participating in local projects—and when their contributions to the process are valued.

The ICBG might not be the only model for implementing change at the local level, and in a way that is welcomed and guided by villagers (since it is in cooperation with improving the quality of life at the village level); but it is a model currently in use and from which lessons and "best practices" may be gleaned and then replicated elsewhere worldwide. In this way, the ICBG contributes to the larger knowledge base of solutions for effective cooperative endeavors between North and South. ■

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Corresponding author:
DJAJA DJENDOEL SOEJARTO, *PCRPS, College of Pharmacy, University of Illinois at Chicago, 833 S. Wood St., Chicago, IL, 60612, U.S.A. dds@uic.edu, doelsoejarto@gmail.com*

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20 The 1998-2003 UIC ICBG is referred to as UIC ICBG Phase I. On 1 October 2003, a new funding as a result of 2003-2008 re-competition was awarded; the 2003-2008 UIC ICBG is referred to as PHASE II. In Phase II, UIC, NCST [this institution name was changed in 2004 to VAST (Vietnamese Academy of Science and Technology)], CPNP, and TMRC continued to be members of the consortium, with Purdue University added as a new member, and Bristol-Myers Squibb (B-MS) Pharmaceutical Co. became the industrial partner.

21 The terms and conditions of Phase II UIC ICBG are, in large part, similar to the 1998-2003 Phase I, with the exception that, in Phase II, each member of the consortium has the right to file an IP protection.

22 In Phase II, the percentages of the royalty stream also flow to Purdue Universty; B-MS waived the rights to any royalties.

23 The accomplishments of the UIC ICBG (Phase I and Phase II) were examined in a 2006 paper: Soejarto DD, HJ Zhang, HHS Fong, GT Tan, CY Ma, C Gyllenhaal, MC Riley, MR Kadushin, SG Franzblau, TQ Bich, NM Cuong, NT Hiep, PK Loc, LT Xuan, NV Hai, NV Hung, NQ Chien, LT Binh, BM Vu, HM Ly, B Southavong, K Sydara, S Bouamanivong, JM Pezzuto, WC Rose, GR Dietzman, BE Miller, and TV Thuy. 2006. Studies on biodiversity of Vietnam and Laos 1998-2005: Examining the impact. *Journal of Natural Products* 69: 473-481.

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