調査報告

米国における遺伝資源の取り扱いについて

調査機関

2013 年 3 月 25 日から 2013 年 3 月 29 日まで

（公開版）

国立遺伝学研究所　知的財産室

ABS 学術対策チーム

森岡　一

2013 年 4 月 10 日

まとめ

米国は生物多様性条約に加盟していない国である。しかし、世界で最も遺伝資源の利用が盛んな国でもある。生物多様性条約フォーラムの外にあって、加盟国である提供国との関係において、生物多様性条約の自国の利用への影響をとらえ、自国の遺伝資源利用を停滞させず発展させているのか日本の今後の ABS 対策を構築するうえで参考にすべき点は多くある。

米国の遺伝資源探索活動は古くから行われている。1970 年代から生物から有用な産物を見出す探索研究が盛んで、抗生物質や抗がん剤など多くの成果を上げてきた。これらの新規な活性化合物を探索する研究の中心は国立衛生研究所（NIH）であり、その中の国立がん研究所（NCI）である。現在でもこの探索研究活動は NIH 予算により継続している。特に、NIH の内部機関である Fogarty Center（国際学術連携機関）が主催する International Cooperative Biodiversity Group (ICBG)の活動は、探索のみならずあらゆる遺伝資源探索を提供国と共同で行い、また米国内の農務省、科学技術院、エネルギー省等と提供国の間の活動を支援している。

NIH の遺伝資源探索プロジェクトを支える基本理念は“Principle”という形で表現されている。この中には、生物多様性条約で求められている基本的な原理、約束事が盛り込まれている。この”Principle”がプロジェクト全体のみならず、プロジェクト成果のライセンス先にまで及んでいる。プロジェクトの資金申請を行う大学はこの”Principle”に従うことを約束させられる。また、成果のライセンス先の企業もこの”Principle”に従って提供国との利益配分交渉をやり直し、たとえ派生物であってもその利益配分は行わなければならない。

NIH の遺伝資源探索研究は次の二つのシステムによりその活動が支えられ促進拡大している。米国の大学といえども提供国と交渉するのは面倒であるし、時間がかかる。一方、提供国のキャパシティービルディングをボランティアで行う米国の弁護士グループがある。NIH とこれらのグループが協力し、探索研究を促進することである。ボランティア弁護士グループとして Public Interest Intellectual Property Advisors（PIIPA）がある。主に、提供国内の特許制度などのインフラ整備を行っているが、NIH と協力して提供国との PIC/MAT 交渉に参加している。このグループの参加によりいままで 2 年かかっていた契約が 6 か月で取れるようになったという成果を上げている。このような専門家からなる中間交渉グループの設立が大きな促進効果をあげていることを認識すべきである。

遺伝資源を利用する学術研究の利益配分は、学術論文の発表、留学生の教育・訓練、提供

国での研究キャパシティの構築などがある。しかし、一般にこれらの活動は遺伝資源探索研究プロジェクト内の費用で賄われることは少ない。プロジェクトとは関係ないという理由で資金はもらえない。NIH のプロジェクトでも同様である。そこで、NIH ではこれらの利益配分活動に対して、NIH 内の教育予算、関連省庁の予算、提供国大使館の予算などを当てているとのことである。こうすることにより、提供国で単に探索研究に終わるのではなくビジネスに結びつけることも可能になった。日本でも SATREPS という JST と JICA を結びつけたシステムをイメージさせる。

米国の学術界での生物多様性条約特に ABS に対する取り組みは、日本同様に未完成の状態である。特徴的な取り組みは Smithsonian 研究所が主宰する生物の DNA-バーコードシステムの導入がある。提供国の遺伝資源を DNA のバーコード化でカタログ化する計画である。学術的に非常に貴重な取り組みであるが、実用的な展開も見せている。すなわち、農産物や海産物の出所偽物対策、森林保護対策、絶滅危惧種（CITES）監視システム、水質検査などに応用されている。そのため、提供国からのプロジェクト依頼が多く、多くの国で様々なプロジェクトが展開している。

学術界での生物多様性条約関連の取り組みは、NIH 関連プロジェクト以外を除くと活発ではない。しかし、AUTM を中心に問題意識が高まっている。やはり、知的財産権や契約を行う実務部署が、一番意欲が高いといえる。ガイドラインの作成などに積極的である。その基本的考え方は簡便性を求めており、ディシジョンツリーのようなフォーマットが適しているとの意見が印象的である。

Signing of Prior Informed Consent for collecting in the Adelbert Mountains of Papua New Guinea. Photo by Barrows ICBG, Papua New Guinea.

目的：

生物多様性条約の取り組みとして 2010 年 COP10 で名古屋議定書が採択され、各国はその批准に向け国内法を整備している。加盟国である日本も名古屋議定書で定められたアクセスと利益配分（ABS）を遵守する義務がある。日本も環境省が主管官庁として精力的に国内措置を検討している。文部科学省が所轄する大学等の学術研究も名古屋議定書の対象になることから、ライフサイエンス課が担当して学術研究の対策を検討している。また JST でも SATREPS という提供国との総合的な遺伝資源開発を運営している。

米国は生物多様性条約に加盟していない。独自の考えで遺伝資源利用研究を実施している。しかし、その米国が対応する提供国はすべて加盟しているので、共同研究などを実施するには独特の経験とノウハウがある。米国のプロジェクトで一番大きなのが NIH（かつて対がん撲滅運動の一環として NCI が開始）の行っている ICBG で、Fogarty センターが主催している。ウエッブサイトで検索すると多くのリーガルインスツルメントが用意されており、多くの実績もある。

名古屋議定書の構内措置に関して米国との関連を考える必要がある。日本が研究者を厳しく縛る国内措置が行われ、米国との競争力を低下させないようにすることが必要である。実際に、大学の研究者より、米国との研究の競争力を失わない観点でも頻繁に質問される。

米国事情を、米国バイオインダストリー協会、NIH の産学連携部、さらに本課題の知識が深い米国弁護士、スミソニアン博物館担当者等から、米国の学術研究が行っている生物多様性のアクセスと利益配分の現状を調査する。具体的な質問事項には、

１）　提供国との交渉にあたっての基本的考え方とその形成方法、どのような部門が関与しているか？
２）　その考え方をガイドラインなどのツールとして作成しているかどうか
３）　その考え方をどのように関係者に周知徹底しているか
４）　その考え方で提供国と交渉したとき問題となった点はなにか
５）　共同研究の成果をどうしているか？

を考えている。

米国訪問先に送付した理由書は下記の通りである。

RE: Plan for US Survey Trip

The Japanese ministry of education, culture, sports, science and technology (MEXT) has established a project called the National Biological Resources Project (NBRP) to promote bioresource research management in Japan. This project consists of many universities and research institutions keeping and using natural biological resources for academic researches.

Many Japanese biological researchers in academic institutions have considered biological resources as their research targets and have been conducting international research collaboration with oversea research institutions. Researchers who conduct research activities with oversea universities have frequently felt that they need to obtain updated information of regulations of the access and benefit sharing under the Convention on Biological Diversity. And they also want to know how American scientists are dealing with biological resources with provider countries.

Under this research circumstances, the National Institute of Genetics has started a new initiative team, the ABS Task Force Team for Academia, as a part of the Project and asked me to manage the team. This new team supports and accelerates academic institutions' implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Utilization under the Convention on Biological Diversity (so-called the Nagoya Protocol).

We, ABS Task Force Team for Academia, believe that it is important for us to meet U.S.A. representatives and ask current situation about academic activities using biological and genetic resources and any implementation efforts of the Nagoya protocol in the U.S.A. This information is useful for us to consider user measures in Japan.

I am now planning to visit U.S.A. authorities and institutions from March 25th to March 30th, 2013. When I visit you, I would like to introduce our activities and ask you to provide us updated information of international academic research collaborations using biological and genetic resources and of access and benefit sharing efforts.

I would like to meet you and make productive discussion regarding academic researches using biologic and genetic resources. I look forward to hearing from you soon.

米国出張予定先とスケジュール

日時	組織	面談者	場所
3 月 25 日 午前 9 時-12 時	Oblon, Spivak, McClelland, Maier & Neustadt, L.L.P. （米国最大特許事務所）	Dick Kelly	1940 Duke Street Alexandria, Virginia 22314 Phone: 703.413.3000 Fax: 703.413.2220 Direct Dial: 703.412.6008
3 月 26 日 午前 9 時-12 時	Venable LLP （遺伝資源契約アドバイザー）	Michael A. Gollin	575 7th Street, NW Washington, DC 20004 T 202.344.4072 F 202.344.8300 Partner magollin@Venable.com
	Public Interest Intellectual Property Advisors（PIIPA）（資源国側契約アドバイザー組）	R. Mark Davis	575 7th Street, NW Washington, DC 20004 Tel: 401-374-0607 Fax: 484-251-7791 rmdavis@piipa.org Skype: piipahq www.piipa.org
3 月 25 日 午後 1 時-3 時	Office of Technology Transfer National Institutes of Health （産学連携室　利益配分関係）	Steven M. Ferguson, CLP	6011 Executive Boulevard, Suite 325 Rockville, MD 20852 Telephone: (301) 435-5561 Fax: (301) 402-0220 Email: sf8h@nih.gov Web: ott.nih.gov
3 月 27 日 午前 10 時 ~11 時	ICBG Program Officer Fogarty International Center National Institutes of Health （ICBG は NRBP と同じような活動）	Dr. Flora N. Katz	Building 31, B2C39 31 Center Drive MSC 2220 Bethesda, MD 20892-2220 Phone: (301) 402-9591 Fax: (301) 402-0779 Email: flora.katz@nih.gov
3 月 27 日 午後 １時~ ３時	科学技術振興機構ワシントン事務所	大濱　隆司 (Takashi Ohama)	Director, Washington, D.C. Office Japan Science and Technology Agency (JST) 2001 L Street NW Suite 1050 Washington, D.C. 20036 U.S.A. Tel: 202-728-0007; Cell: 202-821-3122 http://www.jst.go.jp/EN/
	日本大使館	次田明	Chief of Science Section Science Counselor Embassy of Japan
月 27 日午 後 4	Office of Environmental Quality and Transboundary Issues	Joseph M. Ripley (Joe)	Room 2727 2201 C street, NW Washington, DC 20520 Tel: (202) 647-1804

時~5時30分	Bureau of Oceans, Environment and Science U.S. Department of State Management Team		Fax: (202) 647-1052 E-mail: RipleyJM@state.gov
	Allorney-adviser Oceans, Environment and Scientific Affairs	Oliver Lewis	L/ONE, Suite 6420 2201 C street, NW Washington, DC 20520
	Office of International Health and Biodefense	Gwen Miranda Tobert	Suite 2734 2201 C street, NW Washington, DC 20520
3月28日午前9時~10時45分	USDA/ARS Office of National Programs	Peter Bretting	Room 4-2212, Mailstop 5139 5601 Sunnyside Avenue Beltsville, MD 20705-5139 TEL 301.504.55411. FAX301.504.6191 E-mail:peter.bretting@ars.usda.gov Web site:http://www.ars.usda.gov/research/programs/programs.htm?NP_CODE=301
	USDA, ARS, Office of Technology Transfer Technology Licensing Program Coordinator	Ms. June Blalock, CLP	Room 4-1174, George Washington Carver Center 5601 Sunnyside Ave. Beltsville, MD 20705-5131 Phone: 301-504-5989 Fax: 301-504-5060 Email:june.blalock@ars.usda.gov
	農林水産省農林水産技術会議事務局技術政策課知的財産第2係長	八木橋史子	〒100-8950　東京都千代田区霞が関1-2-1 TEL: 03-3503-8111(内線 5890) 03-3502-7436 FAX:03-3507-8794 E-mail: fumiko_yagihashi@nm.maff.go.jp
3月28日（木）午後0時～2時	Smithsonian Institutetion National Museum of Natural History Executive Secretary Consortium for the Barcode of Life （スミソニアン博物館　バーコード計画 C-BOL 主催者）	David E. Schindel	Room CE-119 10th & Constitution Avenue, NW Washington, DC 20560 Postal mailing address National Museum of Natural History Smithsonian Institution P.O. Box 37012, MRC-105 Washington, DC 20013-7012 202/633-0812; fax 202/633-2938; portable 202/557-1149 Email: SchindelD@si.edu

			CBOL WEBSITE: http://www.barcoding.si.edu Office and overnight delivery address: National Museum of Natural History
3 月 29 日 (金) 午前 10 時 から 11 時	Biotechnology Industry Organization （米国バイオインダストリー協会副会長、国際問題専門）	Lila Feisee Vice President, International Affairs	1201 Maryland Ave. S.W. Suite 900 Washington DC 20024 Tel. 202.962.9502 Fax. 202.488.6301 www.bio.org
3 月 29 日 （金） 午後 1 時～3 時	FDA Advisor	Bruce F. Mackler, Ph.D., J.D.	Cell: 301-529-6984 e-mail: bmackler@brucemackler.net website: www.brucemackler.net

面談内容
Dick Kelly 弁護士
Oblon, Spivak, McClelland, Maier & Neustadt, L.L.P.　米国最大特許事務所

アクセスと利益配分についてのコメントは以下の通り。遺伝資源の研究をすることによって新しい発見があり、それが科学の進歩に貢献する。科学の進歩が人類の福祉に貢献する。人類には提供国も入っている。

アクセスがなければ利益がないのは当然である。アクセスを制限して利益を要求するのはおかしい。アクセスしても利益がでるまでには相当の投資と時間がかかる。この辺を提供国は理解していないのではないか。医薬品の場合、遺伝資源そのものを利用することは全くないといえる。化合物まで利益配分の権利が及ぶとはとても受け入れがたい。

特許法の基本的精神からすると、特許出願に出所開示を求める間違いである。特許法と生物多様性条約を一緒に考えること自体混乱を招くだけで何の利益もない。

特許実務からすると、植物品種保護法(Plant Variety Protection Act)と植物特許法と一般特許法の関係が混乱している。PVPA は農務省の管轄である。二重に権利を所得することが可能である。遺伝子組み換え植物の特許は特許法でないと権利が守れない。PVPA は提出するものに現物を要求されるし、書類も複雑である。このような植物品種保護の仕組みは実務的には大変である。

Michael A. Gollin
Venable LLP（遺伝資源契約アドバイザー弁護士）
R. Mark Davis PIIPA （資源国側契約アドバイザー組織）
Public Interest Intellectual Property Advisors（PIIPA）

Gollin 氏は 1990 年頃から環境法を主体に行動している弁護士である。米国の
CBD-ABS 関連の実務家で、例えるなら米国の炭田（JBA）といえる。
特徴は、提供国側の信頼が厚い。多くの米国での CBD 関連訴訟で提供国側の弁護を務めている。したがって、提供国サイドからの発言が多い。PIIPA の創始者であり、現在も関与している。Gollin 氏の発言内容は以下の通り。

大学はその権威、評判、社会的責任の観点から、遺伝資源の利用研究に責任を持つ義務がある。研究者まかではなく、ルールに則った組織と手順を踏むべきであり、それを指導すべき立場にある。この義務を放棄することは、大学として社会責任を放棄したこと

になる。利益配分も大学の責任で行うべきであり、研究者任せにすべきでない。だいがくとして、例えば留学生の受入れなどできることがあるはずである。大学の社会的責任を果たすことを社会特に提供国に示すための環境保全宣言を出すべきである。その中で最も重要なのは、条約や法律を守るということである。研究者が勝手にするのではなく、研究者を指導し、研究者が行ったことは大学が責任をとらなければならない。研究者が提供国でつかまったら、大学の提供国での評判は大変悪くなり、どんなによいことをしても認めてもらえない。

出所開示については、話題になる以前から出願者に出所情報を聞いて書類に残すことをルーチンにやっている。遺伝資源に関連して出所情報がある場合は、事務所内で使う宣誓書の出所欄項目にチェックさせ保存する。開示がある国に書式を出す場合はこの書類で判断する。ヨーロッパでの出所開示は、単にあるなしだけでよいので、この宣誓書で十分足りる。インドなどでは、この宣誓書に基づいて、要求される書式に書き込むことになる。特許事務所が提供国の信頼を得るためには、この自主的な出所のあるなし表明は効果があり、きちっとした対応をしていることで信頼してくれる。あまり、うるさく詮索されることもない。日本の特許事務所あるいは産学連携の知財担当も自主的な出所調査方式をとるべきと考える。

PIIPA は資源国の知財システムの構築に貢献している。コロンビアとフィリッピンで天然資源とその研究開発活動を調べ、それらを資源化し商用につなげるために必要なインフラ整備計画をまとめた。コロンビアではコーヒーの原産地表明を解決し、お金儲けができるようになった。ボランティアの弁護士が提供国の担当者と協力して行うので、提供国の担当省庁から大変信頼を得ている。

日本からの資金提供を待ちたい。日本にも同じようなシステムを作り協力してやっていきたい。

PIIPA の活動

Fair Access - Just Results!

PIIPA was the first and is the global leader in providing pro bono IP services to developing countries. Despite the growing debate about the complex global role of intellectual property over the past decade, and the diversity of policy initiatives and academic studies spawned by (and contributing to) this debate, little has been done to meet the practical demands of developing countries and public interest organizations

for access to intellectual property expertise on a case-by-case basis.

Wealthier organizations and private industry have access to such expertise, by paying for the services of the intellectual property professionals that are concentrated in developed countries. In contrast, in developing countries, there are few intellectual property professionals and many organizations cannot afford to pay for their services.

Moreover, many intellectual property professionals are ill-equipped to meet the needs of public interest clients. Society benefits when all people have access to good information and competent advice, and fairness dictates that when poor and excluded people are confronted with the very complicated issues involving intellectual property, they should have access to expert advice and representation.

PIIPA was established as an independent international service and referral organization that can help fill the need for assistance by making the know-how of intellectual property professionals available to developing countries. PIIPA's services are practical, not policy-oriented.

PIIPA's goal is to provide balance and information that may help harness the power of informed debate to solve problems, and combat the fear and ignorance that make solutions impossible and lead to protracted disputes. PIIPA's beneficiaries are finding new ways to solve problems in such contentious and difficult fields as traditional knowledge, biodiversity, health, and agriculture.

We are governed by a volunteer board of directors and gain additional guidance from an International Advisory Board comprised of IP thought leaders from every continent. PIIPA is a tax-exempt corporation under Section 501(c)(3) of the U.S. Internal Revenue Code.

NIH 産学連携室
Steven M. Ferguson, CLP

NIH では古くから遺伝資源探索研究が行われ、多くの成果が産学連携でライセンスされている。アクセスについては、NCI が定めた LOC(Letter of Collection)システムが働いている。探索研究の流れは、
NIH 予算で探索プロジェクトを立ち上げ、大学に研究資金を与え探索研究を依頼する。大学が提供国とアクセスと利益配分を交渉する。その際、研究者、産学連携室、研究企画室がお互いに協力しながら交渉を行い、提供国の同意を得る。探索研究ではよく伝統的知識を利用するので、先住民と交渉しなければならない。たいていの場合は代理人を立てて交渉しなければならず、時間がかかる。ヒトの血液、病原体を扱う時は注意を要する。危険であるのと、権利主張をされる場合があるからである。

NIH は LOC に基づき大学側の交渉を管理する。LOC 契約の締結者は三者（NIH-大学―提供国）間で行う。LOC には提供国との利益配分は義務となっているが、金銭的利益についてはほとんどないので、金銭的利益が出た場合（ライセンス等）は再度締結のやり直しとなる。

研究終了後、その成果で特許をとり企業にライセンスしたら、LOC で定めた義務はライセンス先にも移転し、ライセンス先は同じ義務を負わなければならない。したがって、ライセンスを受けた企業は提供者と再度利益配分について交渉することになる。金銭的な利益配分は NIH からできない決まりになっている。国立機関である NIH から提供国に直接お金を渡すのは寄付行為になるからである。金銭的利益は、企業が直接提供国に行うか大学を経由して行うのが一般的である。金銭的利益の配分率は 50:50 が原則だが、交渉で変えることは可能である。

いままで探索研究を 15 年間やってきたが、明らかな成果（新規物質の発見など）がでたケースは 6 件しかない。しかし、それらの化合物には毒性等の問題があり、開発されて市場に出たケースはない。特に NIH がこれらの成果をモニターすることはないが、LOC の利益配分に関する契約を守らない場合は注意を与えることになる。

NCI にある天然資源保存所にあるサンプルを利用してスクリーニングを行うことができる。このプログラムを Open Repository Program という。この保存所からサンプルを入手するには特別な Material Transfer Agreement(MTA)を締結しなければならない。この MTA には関係者全員の権利が保障されている。

NIH が利益配分としてできることは主に教育・訓練である。NCI の天然資源部がプログラムを組み、資源国から研究者を呼び寄せて研修を行っている。これらの予算は NCI が単独で出す場合もあるが、NIH の教育予算から出費する場合も多い。その場合、Fogarty 国際センターが担当する。ようするに、NIH の多くの部門が教育活動を分担することになる。

大学は自身の社会的評価・評判を確保し高めるための政策を推進すべきである。大学が提供国と国際連携を推進するには提供国社会に貢献することになる。その際に、ルールを守ることが求められる。そういう、大学の統制が研究者に行き渡っていて、提供国での大学の評価が高まれば、研究者の探索研究は促進され提供国にも利益が及ぶことになる。

表 1　NIH の遺伝資源研究で使用する"special MTA"の条件

Conditions Of Access To The Active And Open Repositories

Material Transfer Agreement

The staff of the Natural Products Branch will be administratively responsible for the operation of this program. Successful applicants will subsequently deal directly with the Branch to request material and report scientific results.

Organizations and individual investigators whose applications are approved will be provided selected samples under the terms of a Material Transfer Agreement, which has been modified from the standard Public Health Service (PHS) agreement to meet the specific needs of this program. Important aspects of this agreement are:

Recipients must agree to protect the interests of the Countries of Origin providing the materials to NCI.

The NCI will retain ownership of the material per se. Such ownership is separate from intellectual property rights.

The recipient will pay the "out-of-pocket" costs of preparing and shipping samples.

In no case will a sample be provided that depletes the supply of that material or otherwise affects adversely NCI's own efforts.

Unused samples will be disposed of by mutual agreement.

A reporting procedure will be established to assure that NCI is kept informed of the usage of Research Materials. To this end, recipients are encouraged to contact the NPB as early as possible once a particular extract has proven to be of interest in order that

suitable arrangements for further development may be agreed upon by all parties These may include full taxonomic identification; provision of more extracted Research Material; aid in obtaining raw material via the then current Collection Contractors; or the negotiation of a formal Cooperative Research and Development Agreement (CRADA).
Research results derived from this Research Material will be transmitted in a timely manner to the NCI.
A summary of the screening results relating to the Research Material and any purified natural products will be provided to the relevant organizations in the Countries of Origin.
Safeguards will be installed to prevent disclosure of proprietary information during this interchange.
As part of this interchange of information, if a research organization has been identified within the Country of Origin that is actively pursuing studies in the relevant scientific area, then the recipient will be informed with the aim of facilitating collaborative studies.
All test information that is provided to recipient, collector, and the Country of Origin government or an appropriate organization within the Country of Origin is to be maintained as 'CONFIDENTIAL' with any publication delayed until DTP authorizes release to outside parties.
The NCI will not grant unlimited access to Research Materials within the repository. The selection of samples will be determined by the NCI after discussion with the recipient, and the size of samples will be limited to that required for primary and limited secondary testing in the recipient's screens.
Large amounts of raw material required for isolation and development of active agents will generally be obtained by recipients at their own expense and in accordance with established agreements among NCI, its collecting agents and the Source Country Organization. In specific cases, however, the NCI may agree to participate with the investigator(s) in the recollection process to procure additional raw and/or Research Material if the initial findings are scientifically of substantial interest to the program.

遺伝資源に関する特許出願に出所開示を求めることに米国特許商標庁は反対している。特許法の中で出所開示することはふさわしくない。米国特許商標庁は、ライセンスやその他の方法による利益配分こそが最も簡単で適切なことであると考えている。

名古屋議定書が発効すると保存遺伝資源の移転にも影響がでると考えられる。もし、MTA に出所情報を入れその義務を継承するとしたらどうするか課題である。NIH では古くか

ら”special MTA”を定めている。この”**special MTA**”では LOC の義務を引き継いだもので、遺伝資源の移転先にも LOC の義務が移転ことになる。つまり、LOC で定めた利益配分を MTA で遺伝資源を受け取った研究室も負担しなければならない。MTA 自身は NIH が通常使っているものであるが、そこに利益配分義務が付加されている。

NIH　ICBG プログラム[1]本部
Dr. Flora N. Katz

遺伝資源探索研究は 1955 年の NCI プログラムが出発である。その後、プログラムが拡大、進歩し、18 年前から Fogarty センターが遺伝資源探索研究を主宰している。最大の特徴は、NCI 時代は計画から実施まで 2 年かかっていたがいまは半年でできることである。そのためプログラムの運営システムを改良した。

NIH が公募して、大学の提案したプロジェクトの中から最適なものを選ぶ。採用されたプロジェクトに資金提供するときに、生物多様性関連の “**Principles**”について契約する。　プロジェクトを実行する大学はこれに従わなければならない。この “**Principles**”の中には、CBD で要求される ABS 事項が書かれている。

大抵の場合は学術研究だけだが、研究成果で特許を取りそれを企業などにライセンスすると、ライセンス先の企業もこの “**Principles**”に従わなければならない。学術研究では利益配分はそれほど重要視していないので規定は細かくないが、ライセンス先企業が契約する場合は利益配分の条件について再度資源国と交渉することになる。基本的には、利益配分は三者(大学、NIH、提供国)の間で分配することになるが、それぞれの事情を考慮して行う。

大学ができる利益配分は論文発表、教育・訓練などであるが、最初の提供国交渉で何が必要なのか相手に聞くことから始まる。それぞれの国で希望しているものが違うからである。当然当事者となる地域住民などの意見も聞くことにしている。その後、相手側の代表者と交渉し、どういうことがしてほしいのか、どういうことができるのか決めることになる。NIH が直接交渉することはなく、大学の研究企画や産学連携などの担当者が行う。ただし、NIH はこれらの活動を常に管理している。

大学等が行う教育訓練で提供国から研究者や学生を呼ぶが、その費用はプロジェクト費では賄えないので、NIH の別のプログラムの資金で交通費、滞在費だすことが多い。あるいは、学校とか道路建設、研究施設建設などといったものは大学では手におえないので、提供国にある米国大使館と相談して専門家を派遣してもらうようにしている。

[1] http://www.icbg.org/.

最近、NIH の ICBG プログラムが上手くいっているので、他省からも参加要請を受けている。今後は、農務省、科学アカデミー、エネルギー省など（下記）と協力した国際研究協力を行うことになる。

表 2　NIH の ICBG プログラムの資金スポンサー団体

- National Institutes of Health (NIH)
  - Fogarty International Center
  - National Cancer Institute
  - National Institute of General Medical Science
  - National Institute of Mental Health
  - National Center for Complementary and Alternative Medicine
  - Office of Dietary Supplements
- National Science Foundation (NSF)
- US Department of Agriculture (USDA) National Institute for Food and Agriculture
- Department of Energy (DOE) Office of Biological and Environmental Research
- National Oceanographic and Atmospheric Administration (NOAA) Oceans and Human Health Program

こうなるとますます大きなプロジェクトになるので、利益配分として学校を建てたり、電気をひいたりすることもできるようになる。最初に当事者の意見を聞くことが重要である。NIH は直接利益配分にかかわらないが、最初の契約に基づき、すべての活動をモニターしている。国務省も国際関係の問題として遺伝資源探索活動に興味を持っており、研究活動が促進されるようバックアップしている。

現在のプロジェクトは下記の通りである。フィージのさんごプロジェクトではサンゴ養殖を支援して、フィージの国から金儲けの仕組みができたと喜ばれている。

表 3　NIH の ICBG プログラムで減殺進行中のもの

Project tittle	Principal Institution	Principal Investigator	Collaborating Country
Exploration, Conservation, and Development of Marine Biodiversity in Fiji	Georgia Institute of Technology	Mark Hay	Fiji
Discovery of natural product-based drugs from Costa Rica	Harvard Medical School	Jon C. Clardy	Costa Rica
Diverse Drug Lead Compounds From Bacterial Symbionts in Tropical Marine Mollusks	Oregon Health Sciences University	Margo Haygood	Philippines
ICBG: Training, Conservation and Drug Discovery Using Panamanian Microorganisms	Smithsonian Tropical Research Institute	William Gerwick	Panama
Bioassay and Ecology Directed Drug Discovery in Panama	Smithsonian Tropical Research Institute	William H. Gerwick	Panama
Biodiversity Surveys in Indonesia and Discovery of Health and Energy Solutions	University of California, Davis	Daniel Potter	Indonesia
Bioactive Compounds from the Biodiversity of Vietnam and Laos	University of Illinois at Chicago	Djaja Doel Soejarto	Laos, Vietnam
Biosynthetic Analysis of Marine Cyanobacterial Pathways	University of Michigan	David Sherman	Costa Rica
Conservation and Sustainable Use of Biodiversity in PNG	University of Utah	Louis Barrows	Papua New Guinea
Biodiversity Conservation & Drug Discovery in Madagascar	Virginia Polytechnic Institute and State University	David Kingston	Madagascar

NIH の ICBG プロジェクトが成功している要因は、提供国側を支援している弁護士グループ Public Interest Intellectual Property Advisors (PIIPA)の存在がある。大学が提供国と直接交渉してもなかなかうまくいかないし、時間がかかる。PIIPA は弁護士集団であり、提供国側の政府系弁護士も参加しているので、交渉内容はよく把握しているし、経験もある。提供国の弁護士は政府と親密なので本音を聞きやすい。PIIPA が提供国側との交渉の間に入って両者を取り持ってくれるので、交渉がスムースになった。いままでプロジェクトを立ち上げてから開始するまで 2 年かかったが、PIIPA のおかげで 6 か月しかかからなくなった。面倒な交渉もフレンドリーに行える。時には相手側の交渉当事者になることもある。何も知らない提供国に代わっていろいろ交渉をまとめてくれる。

なお PIIPA 本部へは後日訪問する。

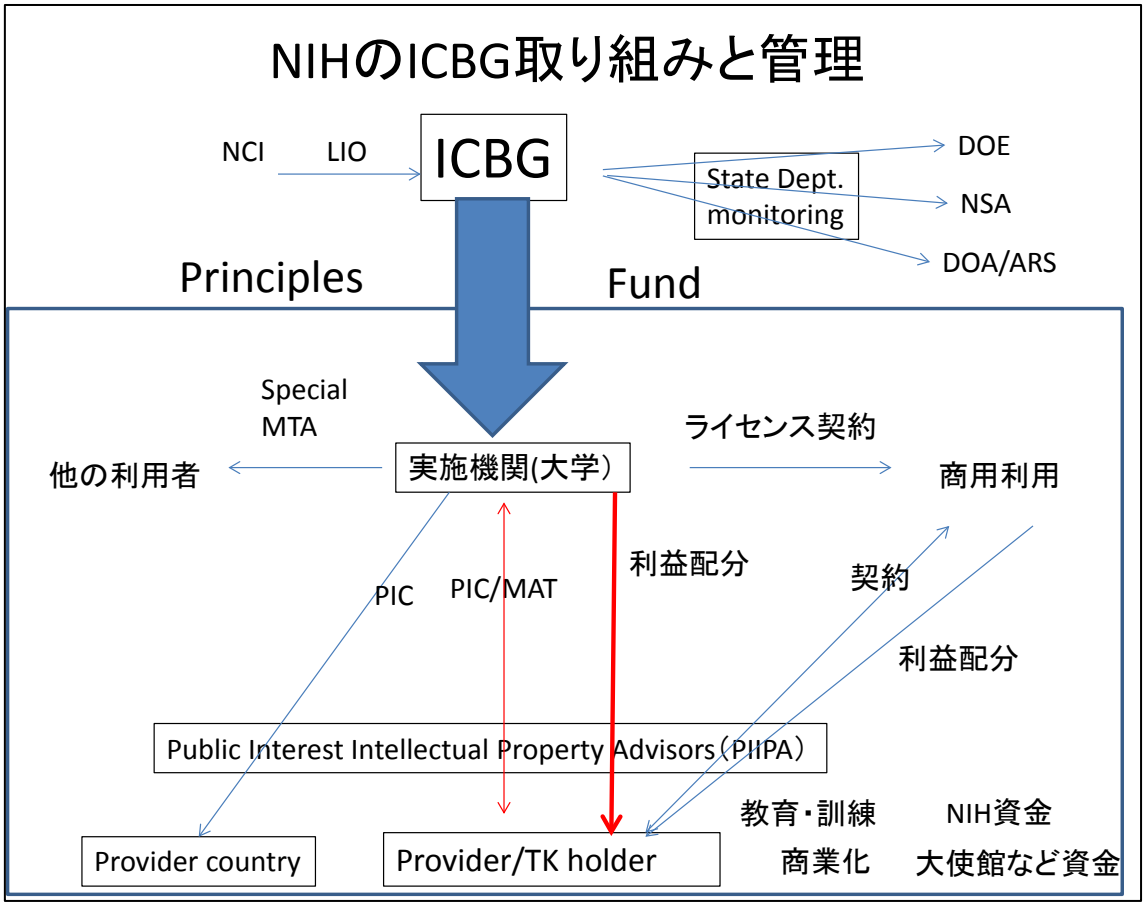

図 1　NIH の遺伝資源探索研究プロジェクト ICBG の仕組みとその基本原理（Principles）

NIH の ICBG プロジェクトの一つであるパナマプロジェクトが名古屋議定書に基づく世界環境ファシリティ基金（GEF）から 100 万ドルの支援を受けた。これはこの名古屋議定書基金の最初の支援である。この基金により、パナマ政府や研究所の能力が高まり、保護海

域の拡大により遺伝資源の保護が広がることが予想される。

科学技術振興機構ワシントン事務所
大濱　隆司（Takashi Ohama）
日本大使館
次田　明（TSUGITA Akira）

今回のワシントン訪問目的の説明と、NIH 紹介のお礼のため訪問した。生物多様性条約の名古屋議定書批准に向けた国内措置検討委員会の活動状況について説明した。日本の学術研究者の迷惑、重荷になるような仕組みは避けるべきである。米国では研究活動が自由にできるので、　アメリカに負けないように仕組みを考えなければならない。学会や学術会議を通じて ABS について普及することも必要であり、そのため学術会議議長から何らかの声明をだしてもらうのがよいのではないかと考える。

米国国務省海洋・環境・科学局
Joseph M. Ripley (Joe)
Management Team
Oliver Lewis
Allorney-adviser
Oceans, Environment and Scientific Affairs
Gwen Miranda Tobert
Office of International Health and Biodefense

国務省では、遺伝探索研究環境が国際的であるため米国の研究者が CBD を知らないで国際共同研究をできる環境ではないと考えている。米国が CBD に入らないのは政治的判断であるが、その判断基準を示すのが国務省である。研究現場では困る事態になってきていると感じている。国務省として問題が大きくなるならばこれを積極的に解決するために行動すべきであると考えている。また、国会を動かすためには世論を盛り上げる必要がある。今は情報収集・分析のときである。

研究者に ABS 教育するにもなかなか機会がないのが現実である。大学ではなかなか必要性をわかってくれない事情もある。NIH が行っている ICBG プログラムを拡大してきているので、関係する大学でも国際学術交流が CBD の規則に則って行われるようにしていきたいと考えている。

NIH は ICBG プログラムやその他のプログラムで国際学術交流は活発であるが、他の大学は日本並みである。したがって、日本の大学がどのように国際交流の中に CBD を取り入れ

てやっていくのか注視していきたい。特に名古屋議定書を日本が批准してどのようにシステムを整えていくのか興味があり勉強していきたい。

日米の学術交流として、日本に保管されている他国で収集した遺伝資源を物質移転契約（MTA）で米国に移転された場合、名古屋議定書批准のあとは日本の MTA に PIC や出所開示があると米国の研究者もこれに従わなければならないことになるのではないか。MTA に付随した条件は移転されると考える。これは米国の研究者を制限することになるので大変困ったことである。学術研究はオープンであるべきで、論文発表後はその研究材料は自由に制限なく交換するのが原則である。

米国の研究者が、遺伝資源の研究発表を行い、データベースを公開する。そうすると、そのデータベースは公開なので、世界中のだれでもみれるようになると、その出所についていろいろ憶測を生み、時にはスキャンダルになる可能性を秘めている。学術研究のオープン性を制限することになるので、対策を考えたいと考えている。米国そのものが世界の中で弱い立場になるのは避けなければならない。

農務省農業研究サービス（DOA/ARS）
Peter Bretting
Ms. June Blalock, CLP
農林水産省留学八木橋氏

農務省農業研究所が所有する生殖体の分譲がメインの役割である。管理部門として、現在 ITPGRFA 関係の取り組みを行っているが、CBD も関連あるので、活動はしている。Bretting 氏はナショナル植物遺伝資源システムのプロジェクトを統括するプロジェクトリーダーである。Blalock 氏は技術移転担当である。Bretting 氏と Blalock 氏は ITPGRFA の交渉に関わったそうである。

ITPGR では非金銭的な研究機関間の協力、能力開発等が組み込まれている。実際に農業関係では、教育・訓練、データベース開発の手伝いをしている機関もある。CBD でも非金銭的利益は学術研究の本来の姿であるので、強調すべきである。

スミソニアン協会　DNA バーコード計画 Consortium for the Barcode of Life（CBOL）主催者　David E. Schindel

DNA バーコード計画は CBD の名古屋議定書以後多くの提供国で認識が広まり、受け入れられるようになった。Sloan-Kettering の資金で 2003 年から DNA バーコード計画 C-BOL は始まった。現在プロジェクトの一つとして Moorea Barcode Project がタヒチで行われている。タヒチの Moorea 島のエコシステムを構成する生物を DNA バーコード化し、環境保全に役立てたいと考えている。研究資金は Gordon and Betty Moore 財団から約 520 万ドルを受けている。

プログラムを継続するため、今年から多くの資金を求めて活動方針を変えた。積極的に DNA バーコード計画の利用価値を宣伝し、多くの利用可能性を追求することにした。その一つとして、Google から資源国で DNA バーコード計画を実施し成功したら資金援助を受けることになっている[2]。Google のグローバル インパクト アワードから 300 万ドルを利用して、世界で絶滅の危機に直面している野生動物を保護するために DNA バーコーディングを開発し、導入を行う。CBOL は、6 か国の開発途上国の研究者と協力して、DNA バーコードの公開ライブラリを構築し、法執行機関が差し押さえた動物の識別に使用できるようにする。

世界中の 180 万の命名種のうち、35,000 種以上が、地域的または世界的に絶滅の危機にあるとみなされている。このうち 2,000 種が、国連の絶滅のおそれのある野生動植物の種の国際取引に関する条約（CITES）の厳しい売買規制によって、不正な国際取引から保護されている。国境を越えて輸送される野生動物を押収し、貿易商を訴えることが、違法取引の抑制に重要であるが、現在の検出ツールは、時間がかかり、信頼性が低く、保護対象種の最も多い提供国では高価すぎたり、入手したりできない。DNA バーコーディングは、短い DNA 配列をグローバル データベースと照合することで、種を識別できるので、コスト効果が高く、迅速な標準的方法となる。CBOL は、研究者と共同でデータベースを収集し、法執行官を訓練する予定で、このテクノロジーでの違法取引の根絶を目指している。

このような経過から、ABS 問題に積極的に取り組むことになった。パイロットプロジェクトとして、南アフリカの穀物病の検出に DNA バーコードを利用する計画、メキシコの伝統的医薬の公正な運用をするための利用計画などを実施している。伝統的医薬では偽物が多いので、それを区別する必要がある。輸入される魚の出所検出にも利用する計画もある。

[2] http://www.google.com/giving/impact-awards.html.

いくつかの提供国の当事者との話し合いで ABS 問題が重要であることを認識した。現在 ABS のためのガイドラインを開発し、投稿中である。（入手希望）スイスも同様なアプローチを考えているようである。このガイドラインのポイントはディシジョンツリーという方式である。いろいろな研究者が ABS ガイドラインを読むことになるので、それらの研究者すべてに対応したガイドラインは膨大になる。最小限の情報入力で自分に必要な情報に行き着くために、条件によって振り分けるのがよい。必要ないところを読んでもらうことはなく、いくつかの質問に従って振り分ければよい。単に純粋基礎研究者に特許出願まで読ませることはないと思う。

資源国とは PIC と MAT を別々に結ぶが、そのやり方はおかしい。両方を一つにして行うべきである。MAT で常に課題となるのが、商用利用への変換、第三者への移転、学術発表のやり方である。商用利用については、トリガーポイント（どういう事態になれば商用とみなすかの条件）を決めていることが多い。大抵の場合、非営利研究の契約では、契約に条件を定めて、それを越えた場合は別契約にするという条項が入っている場合が多い。9 割以上の非営利研究ではその条件に達することはないので、最初の研究にいちいちトリガーポイント以降に起こることまで契約に組み込むことを最初から行うのは交渉時間の無駄である。

八木橋氏報告

大学共同利用機関法人情報・システム研究機構国立遺伝学研究所知的財産室 ABS 学術対策チームチームリーダー森岡一氏とバーコードオブライフコンソーシアム（CBOL）事務局長デイビット・シンデル博士「生物の多様性に関する条約（CBD）の遺伝資源の取得の機会及びその利用から生ずる利益の公正かつ衡平な配分（ABS）に関する名古屋議定書」に係る打ち合わせ概要

日時：平成２５年３月２８日　午前１２時～午後１時１０分（米国東海岸時間）
場所：スミソニアン博物館自然史博物館
出席者：
（日本側）国立遺伝学研究所森岡 ABS 学術対策チームリーダー
（米国側）スミソニアン博物館 CBOL 事務局デイビッド・シンデル事務局長

[背景]

２０１０年１０月に日本で開催された CBD の第１０回締約国会合において、ABS 名古屋議定書が採択されたことを受け、日本政府は当該議定書に関連する省庁間の作業部会を設置し、批准に向けての作業が進めているところである。その一環として、文部科学省が実施するナショナルバイオリソースプロジェクトの中の一実施機関である国立遺伝学研究所知的財産室に ABS 学術対策チームが設置され、チームリーダーである森岡一氏が、今後の日本国内における名古屋議定書に沿った学術研究用のガイドラインを作成する際の参考とするため、３月２５日から３１日の間、多くの遺伝資源を保有し、かつ世界をリードする遺伝資源に係る学術研究が行われている米国を訪れ、関係各機関を訪問しインタビューを実施した。

当方が米国において実施している調査と、森岡氏が実施するインタビューは主旨及び目的が同じであるためインタビューに同席を希望し、承諾して頂いた。

[シンデル博士とのインタビュー概要]
（森岡氏）ABS 名古屋議定書への対応としてバーコードは一つの選択肢と考えている。ABS に係る CBOL の活動について教えて頂きたい。
（シンデル博士）CBOL の活動は、スローン財団の基金を基礎として、研究資源のバーコードを促進する狙いで 2004 年より 8 年間のプロジェクトとして始まった。データベースのデータベースという性質を持ち、魚のバーコード化が代表的なものである。当該プロジェクトについては、一定の成果を上げて 2012 年に終了を迎え、次の研究フェーズに入っている。現在のプロジェクトは、グーグル社からのクローバルインパクトアウォードとして 3 百万ドルの資金援助を得て実施している。５つの優先項目を立て、その中の１項目が ABS に関連している。CBOL としては、CBD の会合では当初は、サイドイベントに参加する程度で、交渉には深く関与（involve）していなかった。しかし CBD 締約国会合の下で ABS に係る交渉の作業部会が設置されたことを受け、学術界として 2008 年にドイツで非商業目的の研究のための国際的なワークショップを開催したことをきっかけに、関与するようになった。基礎的な学術研究に対する特別な配慮については、名古屋議定書第 8 条において考慮されていると考えている。上記プロジェクトの中で、特に医薬品用の植物遺伝資源に係る ABS のプロジェクトを実施している。医薬品用の植物遺伝資源は、名古屋議定書においても配慮しなければならない伝統的知識（Traditional Knowledge）が含まれていて、取り組むのに価値があるテーマだと考えた。プロジェクトの中では、３つの国（メキシコ、ケニア、ナイジェリア）に対象を絞り、ABS の相互に合意された条件（Mutually Agreed Term）に係る選択項目（decision tree）を作成し、それに基づく、素材移転契約を結ぶことを考えている。選択項目の作成については、CBD の ABS に係るナミビアの交渉官であるピエール・ド・プレシス（Pierre du Plessis, CRIAA SA-DC）と協同して作業を実施している。ドラフトが出来たらお送りする。CBOL としては、基礎的な学術研究に支障を来さない枠組みを作ることが重要と考えている。米国は CBD の締約国ではないが、国際的な法的枠組みを遵守する必要があり、それがより簡素で、迅速な方法で実施できる方法を検討している。

（以上）

米国バイオインダストリー協会　Lila Feisee　副会長、国際問題専門

米国でも、大学の研究者が探索研究活動している。あまり ABS のことは知らないようだ。研究者は個別に研究しているので、誰かがチェックすることが大事である。まず研究者に ABS の必要性を認識してもらう努力が必要だ。その後、やはりガイドラインを作らなければならないだろう。米国では、大学のライセンス部門の協会 AUTM がこの問題に熱心であるので、AUTM と協力してやるのはどうか？ライセンス部門は ABS の重要性をよく理解し

ているはずだし、実際に契約を担当するのはこの部門である。例えばカリフォルニア大 Davis 校の Janna Tom やバージニア大の Wriston “Mark” Crowell が詳しい。紹介する。

話が進んでよいガイドラインができたら、来年の BIO ミーティングでワークショップをする案はどうか。3 月 27 日まで東京の外務省非公式ミーティングに出ていた。なかなかよいミーティングであった。

EU から Trusted Collection のアイデアがだされているが、日本でも遺伝研がそうなるのか。NIG、理研、NITE がその候補になるだろうが、ABS 国内措置制度の整備が済んでからでないと難しいのではないか。

企業はかなり ABS の怖さを知っているので、勝手なことを自社の研究者にさせない。会社の名誉と社会責任の問題があり慎重である。したがって、以前ほど企業が遺伝資源探索研究を行うことはなくなった。企業は、大学から新規化合物のライセンスを受ける。その時、その化合物が遺伝資源から派生したとき ABS との関係で問題になる。ABS について PIC/MAT を大学がきちんとやっているかを確認してからでないと企業は大学からライセンスを受けない。現在ある MAT も企業向きでない。利益は将来のことなのに、利益確保したように契約するのは間違いだ。企業は、大学の MAT 契約のやり直しなどややこしいことに首を突っ込みたくないし、もっと今後の開発にお金を使いたい。

WIPO での出所開示の問題も頭が痛い。WIPO の米国代表団に入っている。問題は出願時点で問題が発覚することだ。その時では修復するのに時間がかかり、特許出願の意味がなくなる。また特許出願時の要件ではあるが、その要綱、運用ができていない。特許と引き換えに無理な契約をさせられるのは問題である。伝統的知識も全く問題解決の糸口さえない。WIPO で今後話し合うことになるが大変難しい。

FDA アドバイザー　Bruce F. Mackler, Ph.D., J.D.

米国の製薬会社は天然物から新規物質を見つける探索研究はもう下火になった。金がかかる割には成功することはめったにないからである。国立がん研究所のような所でほそぼそとやっているだけだ。製薬会社はあまり CBD を気にしていないように見える。むしろ、資源国から余計なことをいわれて金をとられたり、強制実施権のようなものを発動されたりするのを恐れている。

伝統医薬の認可を規制する法律はあるが、米国で伝統医薬の開発はそれほど盛んに行われているとはいえない。伝統医薬について FDA が考える最大の問題点は品質の安定性である。

同じ製品が cGMP 準拠条件で安定して製造できなければ薬として売れない。伝統医薬会社はそれが難しく、原料の品質によって変わる。

仲間の広がり

アメリカ大学法学部教授 Snape から始まったコンタクトの広がり

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and
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Technology Licensing Program Coordinator
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Email:june.blalock@ars.usda.gov
Both Dr. Bretting and Ms. Blalock have been involved in the CBD negotiations for many years and can inform you of USDA-ARS policies on germplasm exchange.

US Department of State(訪問済み)
Mr. Joseph Ripley
US State Department
Washington, D.C.
Email: RipleyJM@state.gov
The US Department of State is the lead agency in the US for the CBD and the Nagoya Protocol. Mr. Ripley is the lead person on these issue at the State Department.

Smithsonian Institution
Dr. Leonard Hirsch
Senior Policy Advisor
Smithsonian Institution
Washington, D.C.
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He has been working with ABS issues for many years and has served on the US delegation to the CBD.

PIIPA Mark Davis から始まったつながり

Maria Julia Oliva <julia@ethicalbiotrade.org>

Ms. Maria Julia Oliva –
Senior Adviser on access and benefit sharing
Ethical BioTrade


Dear Maria Julia,

Mark Davis からのメール

I would like to introduce you to Dr. Hajimu Morioka. He is the Team Leader for the ABS Task Force Team for Academia
at the National Institute of Genetics in Japan. We recently met with him at our offices in Washington to discuss ABS agreements and processes under the Convention on Biological Diversity. He is interested in learning more about this topic to ensure that Japanese researchers meet international guidelines when accessing genetic resources in other countries. We felt that you would be a good resource for him in this area.

The Japanese ministry of education, culture, sports, science and technology (MEXT) has established a project called the National Biological Resources Project (NBRP) to promote bioresource research management in Japan. This project consists of many universities and research institutions keeping and using natural biological resources

for academic researches.

Many Japanese biological researchers in academic institutions have considered biological resources as their research targets and have been conducting international research collaboration with oversea research institutions. Researchers who conduct research activities with overseas universities have frequently felt that they need to obtain updated information of regulations of the access and benefit sharing under the Convention on Biological Diversity. And they also want to know how scientists are dealing with biological resources with provider countries.

Under this research circumstances, the National Institute of Genetics has started a new initiative team, the ABS Task Force Team for Academia. This new team supports and accelerates academic institutions' implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Utilization under the Convention on Biological Diversity.

Maria Julia Oliva からの返事とそれに対する返事

Dear Dr. Morioka,

It is a pleasure to make your acquaintance through Mark's kind introduction. I have actually just returned from Tokyo, where I participated in an expert meeting organised by the Ministry of Foreign Affairs, in collaboration with the United Nations University and the Convention on Biological Diversity. The expert meeting focused on best practices on ABS, including in the research sector. We should be receiving a report soon, which I will be happy to share with you.

More generally and if it is of interest, I am happy to share the work on ABS of the Union for Ethical BioTrade (UEBT). I am enclosing an overview of the UEBT and our work on ABS, which may provide you a brief introduction. I am also sending you the agenda for the UEBT annual conference, which is taking place on 19 April in Paris and will have several sessions focusing on ABS.

Best regards,

Julia

Dear Julia

Thank you very much for your kind introduction of the UEBT. I will digest the information you provided when I return to Japan. It looks very interesting since I have tried to set up a similar organization in Japan. Unfortunately, my plan was not supported by Japanese government so it does not exist due to finance. But I still keep in mind and if chance comes, I try again.
We seem to miss meeting in Tokyo. I know the Foreign Affairs Ministry Meeting in Tokyo since I learned from Ms. Susette Biber-Klemn fom Swiss when we held a meeting in February. Though I missed the meeting, my boss, Dr. Suzuki from the National Institute of Genetics, attended it and probably obtained a brochure.
Thank you for inviting me to the meeting on April 19. It looks very interesting, but on that day, we will have a group meeting to discuss academic ABS guideline. But I have a plan to visit Europe and discuss ABS matters with experts in Europe. May I put your name on a list? Probably, I try to visit Europe late September or early October. Before that, I have to hold a meeting in August, inviting Thai government officials and professors of Thai Universities and discussing mutual issues of ABS.
I am really interested in your ABS activities so please keep in touch for exchange of information. After returning to Japan, I will provide you of some information about our activities.

Hajimu

Union for Ethical BioTrade
Launched in October 2007, the Union for Ethical BioTrade is a non-profit association that promotes the 'Sourcing with Respect' of ingredients that come from biodiversity. Members commit to gradually ensuring that their sourcing practices promote the conservation of biodiversity, respect traditional knowledge and assure the equitable sharing of benefits all along the supply chain.

To bring together actors committed to Ethical BioTrade and to promote, facilitate and recognise ethical trade practices in goods that meet the sustainable development goals in the Convention of Biological Diversity
Increased trade in biological resources actively contributes to the conservation and sustainable use of biodiversity, as well as to other sustainable development goals.

Anatole Krattiger anatole.krattiger@wipo.int
WIPO – Anatole Krattiger, Director
Global Challenges Division
34, chemin des Colombettes
CH - 1211 Geneva 20

Biotechnology Consultant To Lead WIPO Global Challenges Division
A leader for the World Intellectual Property Organization Global Challenges Division – tasked with connecting intellectual property to critical issues such as public health, food security, and climate change – has been named more than a year and a half after the division's creation.
Anatole Krattiger, a citizen of Switzerland, arrived in Geneva recently to take up the position of Director, Global Challenges Division. This division grew out of Director General Francis Gurry'sgoal upon taking office in 2008 to "demonstrate the concrete relevance of intellectual property to the global challenges of climate change, desertification, epidemics, access to health care, food security and the preservation of biodiversity."
Krattiger holds a PhD from Cambridge University in genetics and biochemistry, specialises in agricultural biotechnology, and used to be a farmer in both Switzerland and in southern France, according to aprofile [pdf] from Franklin Pierce law school.

More recently, he was a professor in the United States at both the Biodesign Institute at Arizona State University and at Cornell University. At Arizona State he co-taught courses on innovation management and controversies in health and agricultural biotechnology, according to his profile at the university. Also at ASU, he worked on the "intellectual property component of plant derived pharmaceuticals and vaccines," according to his LinkedIn profile. At Cornell, where he worked for 18 years, he co-taught a course in Patents, Plants and Profits, according to the LinkedIn profile.

Also on the LinkedIn profile, he lists his interests as the "international dimension of technology transfer" and "use of appropriate technologies to alleviate poverty in health and agriculture," and says that he "manages the global access strategy of a Bill & Melinda Gates Foundation-funded program for the development of pneumonia and meningitis vaccine for newborns."

Krattiger served as an executive to the Humanitarian Board for GoldenRice, working on licensing, technology transfer, patent pooling and regulatory issues, according to several sources. GoldenRice is controversial rice variety genetically modified to produce higher levels of beta-carotene, necessary for the production of Vitamin A. Questions have been raised about efforts funded by the Rockefeller Foundation and the Swiss government to promote this non-traditional form of rice in the global South, which comes with many patents owned by companies in developed countries. Krattiger consulted for the Rockefeller Foundation on health, agriculture and innovation.

Krattiger assisted in the founding of the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), according to the ASU profile. ISAAA is a non-profit aimed at sharing "the benefits of crop biotechnology to various stakeholders, particularly resource-poor farmers in developing countries, through knowledge sharing initiatives and the transfer and delivery of proprietary biotechnology applications," according to its website. He consulted for the Rockefeller Foundation on health, agriculture and innovation.

Krattiger is a member of the Advisory Council at Franklin Pierce Law Center in Concord, New Hampshire, a law school specialising in intellectual property; a contributing author to the IP Handbook, an online resource for IP policymakers; president and founder ofbioDevelopments-International Institute, a non-profit working in innovation and IP; the editor-in-chief at Innovation Strategy Today; and speaks German, English, French, and Spanish. He has published on a variety of biotechnology matters, from scientific and policy angles.

コロンビア Andrea Bonnet, andrea.bonnet@cancilleria.gov.co

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To Mark, 自分

Dear Mark,

Thank you very much for this introduction to Dr. Morioka.

I would be very glad to talk about it with him. I am available to share our national policy framework with him or any other information he might need.

Best regards,

Andrea Bonnet.

ペルー Andres Valladolid avalladolid@indecopi.gob.pe

Sr. Andres Valladolid
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National Commission against biopiracy Peru
National Institute for the Defense of Competition and the protection of the Intellectual Property –INDECOPI
Presidenta de la Comisión Nacional
President of the National Commission:
Teléfono: 224-7800 Anexo: 1283 / Fax224-0348
Dirección: Calle de la Prosa N° 138, San Borja, Lima 41 – Perú

Dear Mark,

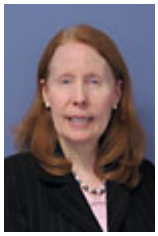
Gladly I am available to help to Mr. Morioka. He can ask me all the information that he needs.

Best regards,

Andres Valladolid

Johns Hopkins 大 Leigh A. Penfield,　lpenfield@jhmi.edu

Johns Hopkins University　Licensing and Commercialization Team



Leigh A. Penfield
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BIO 副会長 Lila Feisee から紹介された AUTM メンバー

Lila Feisee の AUTM メンバーへの紹介文

Lila Feisee <lfeisee@bio.org>
To:
"Soderstrom, E Jonathan" jon.soderstrom@yale.edu>,
"Loise, Vicki - AUTM" <vloise@autm.net>,
"W. Mark Crowell (mcrowell@virginia.edu)" <mcrowell@virginia.edu>,
Janna Tom <Janna.Tom@ucop.edu>,
Robin Rasor <robinlr@umich.edu>,
Kathy Ku <kathy.ku@stanford.edu>,
Ashley Stevens <astevens@bu.edu>,
Lita L Nelsen <lita@mit.edu>

As you know, the Nagoya Protocol for access and benefit sharing has been signed and is being implemented by dozens of countries. The EU and Japan for example are putting in place implementing regulations. Accordingly, there is a big movement in countries to develop what is called “trusted collections” that can be accessed by research organizations and companies. In most settings a trusted collection is one which can guarantee compliance with the Nagoya protocol. Non-compliance with the Nagoya protocol in some countries such as China, India and Brazil among others, can result in patent denial, revocation and in some instances criminal penalties.

My friend Hajimu Morioka of the Japan National Institute of Genetics intellectual property unit, has pulled together a group that is writing guidelines for academia and research entities to ensure compliance with the Nagoya protocol. I thought it might be good to put him in contact with AUTM as universities are generally the front line for access to many genetic materials. Perhaps there are some synergies that can be exploited.

Let me know if I can help facilitate a meeting or conference to discuss this.

Kind regards,

Lila Feisee
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Vicki L. Loise, CMP, CAE
Executive Director
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Wriston “Mark” Crowell <wc8u@virginia.edu>

Exe Dir for Innovation Partnerships & Commercialization
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- wc8u@cms.mail.virginia.edu (registered)
- mcrowell@Virginia.EDU (alias)

Home Page: http://innovation.virginia.,edu

Crowell, Wriston (wc8u)
3 月 30 日 (6 日前)
To Lila, Ashley, E, Vicki, mcrowell, Janna, Robin, Kathy, Lita, 自分, harsy, geoff

Agreed Lila and Ashley. It's important for our membership to stay well-informed and well-ahead of the learning curve on this.

Good suggestion.

Best,
Mark

All, I am also cc'ing Roy Zwahlen from BIO on this email chain. Thanks!!

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Thanks Lila. I agree.

One of the attendees at AUTM Asia last week in Kyoto was a very nice Aussie named Geof Burton with the United Nations University Institute of Advanced Studies who is on assignment to the Nagoya group. He connected with Steve Harsy of the U. of Wisconsin Madison, who is AUTM's MTA guru, and they were happily discussing these issues as we toured some of Kyoto's shrines.

Best regards,

Ashley

Past President
Association of University Technology Managers

Thanks Ashley. I know Geoff Burton well! In fact, I was with him in Tokyo on a quite related issue last week. By the way, I meant to say that I will facilitate a conference call—not a conference!

参考資料

NIH の ICBG Principles

Principles for Accessing Genetic Resources, the Treatment of Intellectual Property and the Sharing of Benefits Associated with ICBG-Sponsored Research

In developing both research plans and appropriate intellectual property agreements, it is important that all involved understand the differences between patent coverage and benefit-sharing agreements. While legal protection of the right to commercialize an invention is generally accomplished through the patent system, agreements among collaborators are generally required to designate the terms of partnerships including, among other things, the licensing of an invention and the sharing of any financial benefits that accrue from it.

The conduct of ICBG-sponsored research and the agreements among the collaborators must address the following principles to be eligible for funding.

1. Disclosure and consent of indigenous or other local stewards.
   a) Plans to collect samples for drug discovery or for other potentially commercializable agents should be vetted with the national government authorities of the host country and with any other organizations they, you or your partners deem appropriate at the earliest stage of planning and once again, formally, before any collections take place.

   b) Where national governments do not have clear regulations to guide informed consent procedures, activities should follow a two phase approach to distinguish basic and commercial research. Basic research intended primarily for publication, including collecting and analyzing biodiversity, including bioassay and chemistry work, may be considered "basic" research for the purposes of this program. If, at any time, researchers intend to file a patent application based on this work or to send a sample for testing to an industrial partner, the research immediately enters the commercial realm for the purposes of this program and must follow all the requisite permit and contract standards of the host country.

c) Arrangements for the use of traditional knowledge or the collection of samples from the lands of local peoples should be based upon full disclosure and informed consent of those peoples. Under best practices such arrangements develop as a partnership with early and ongoing full participation of community representatives in project design.

d) Indigenous concepts of intellectual property should be respected. If, for instance, cooperating indigenous groups, on the basis of religious or other concerns, object to specific uses, widespread dissemination or other treatments of the knowledge or resources they provide, these concerns should be respected in the conduct of ICBG projects.

e) The process of disclosure and informed consent should be as inclusive and formal as is possible and culturally appropriate. The best practice is the development of written agreements with a community following complete and formal mutual agreement and understanding of the Group's goals and methods. Presentations by scientists to host country stakeholders should provide realistic descriptions of the type, amounts and probabilities of benefits, as well as any costs or risks that may accrue to cooperating communities or organizations. Arrangements with individuals who cooperate or provide information should be based upon prior community-level agreements whenever possible or appropriate.

2. Clear designation of the rights and responsibilities of all partners.
a) This is principally done through the design of adequate contractual agreements. Agreements should be among all collaborating organizations, whether or not they are recipients of government funds. These may include commercial drug developers, source country and U.S. research institutions, and indigenous and local peoples whose resources, biological or intellectual, are utilized in the research process.

b) It is strongly recommended that all parties to agreements have separate, competent legal counsel to represent their interests.

c) Useful contractual tools for the designation of rights and responsibilities include material transfer agreements, research and development agreements, license options agreements, know-how licenses, benefit-sharing agreements, and structured trust funds.

d) Unless stipulated otherwise in agreements among source country institutions and their collaborators, biological samples and associated information collected under ICBG-sponsored research is the property of the source country institutions. The US Government retains "march-in" rights to require licensing if the inventing organization(s) fail to pursue development of the process or invention or discovery (e.g. process), as described in the "Terms and Conditions of Award."

e) The ownership and compensation terms of first generation and subsequent inventions based upon a lead discovered in ICBG work should be clearly stipulated in agreements.

f) Agreements should specify that the basic goals of the collaboration include biodiscovery for therapeutic, agricultural and/or energy-related agents, economic development, and the conservation and sustainable use of biological diversity.

g) Agreements should also indicate how a sustainable source of materials for follow-up analysis of a lead compound will be developed, and should preferentially use the participating country and/or communities as the first source of raw or processed materials.

3. Protection of inventions using patents or other legal mechanisms.
a) Non-profit organizations (including universities) and small business firms retain the rights to any inventions resulting from U.S. Government contracts, grants, or Cooperative Agreements consistent with the Bayh-Dole Act and its implementing regulations (35 USC 200-212; 37 CFR 401). PL 96-517, through regulation, extends to businesses of any size the first option to the ownership of rights to inventions made in the performance of a federally-funded contract, grant, or Cooperative Agreement. All group members, therefore, including businesses of any size, might be full partners in the research of the Group and in rights to file patents for any inventions resulting therefrom as specified in the Group's research agreement. This includes communities organized into or represented by an appropriate legal entity.

b) The specific intellectual property arrangements among the institutions may vary and could include joint patent ownership, exclusive licensing arrangements, etc., ., consistent with the Bayh-Dole Act. Valuable intellectual resources that

cannot or will not be patented, such as novel assays or traditional medicinal techniques, may require alternative protection methods, such as trade secrets. You are encouraged to develop an arrangement that best suits the particular circumstances of your Group.

4. Sharing of benefits with the appropriate source country parties.
   a) Benefits that emerge from an ICBG should be considered thoughtfully by the Group, and may include financial benefits from a commercial relationship or product, as well as training, targeted research to address local priorities, and the establishment of long-term partnerships, among other types.

   b) Equitable distribution of financial or other benefits that flow from a commercial relationship or product should accrue to all those who contribute to the relationship or product, whether they are members of the consortium or not, including research institutions and local or indigenous people who provide useful traditional knowledge.

   c) Benefits should flow back to the area in which the source plant, animal or microorganism was found, in such a way that they at least indirectly promote conservation of biological diversity.

   d) The selection of beneficiaries must be justified in terms of program goals, as well as local and international laws and customs.

   e) Benefits should be structured such that they are appropriate to the needs of the communities and the resources of the other collaborators. For example, trust funds managed by a community or community-project board may be more effective in support of conservation and health or education services than cash payments to a single individual or authority.
   f) Ideally, compensation begins flowing early in the collaboration through initial payments, training, equipment or services, to provide near-term conservation incentives.

5. Information flow that balances proprietary, collaborative and public needs.
   a) Agreements and research plans should anticipate the tension between the traditional scientific ethic of public access to information, including publication of results, and the understandable desire of indigenous or commercial partners for

confidentiality of information with potential commercial value, pending protection through patenting or other means. While proprietary needs often require at least temporary confidentiality, you are strongly encouraged not to withhold research results beyond those which are likely to be commercialized or would harm the interests of project stakeholders in identifiable ways.

b) Sharing of information among collaborating organizations should be an ongoing and regular process and should be as complete as possible to maximize efficiency of research and equity in partnerships while recognizing the proprietary concerns of those partners. Reporting back to collaborating communities, where relevant, on significant project developments should be a regular and expected component of the project.

6. Respect for and compliance with relevant national and international laws, conventions and other standards.
   a) Relevant international conventions, such as the U.N. Convention on Biological Diversity and national laws regarding study, use and commercialization of chemical, genetic, biological and cultural resources, should be observed rigorously in the development of agreements and the conduct of research.

   b) An essential goal of this program is to develop models for sustainable and equitable commercial use of biodiversity-rich ecosystems. As such, ICBG research agreements and activities should, wherever possible, go beyond the minimum legal standards regarding international research collaborations, looking to codes of conduct and other standards for guidance. In this regard you are encouraged to review the U.N. Biodiversity Convention's Bonn Guidelines on Access and Benefit-sharing: http://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf.

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the Notice of Award. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm) and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm) .

NIH-NCI の Model Letter of Collaboration

Model Letter of Collaboration between the Developmental Therapeutics Program Division of Cancer Treatment/Diagnosis National Cancer Institute, United States of America (DTP/NCI) and a Source Country Government (SCG)/Source Country Organization(s) (SCO)

http://www.wipo.int/tk/en/databases/contracts/texts/nciloc.html

Subject matter	Plants, microbes and marine macro-organisms.
Summary of use(s)	DTP/NCI will screen the extracts of all material provided for anticancer and AIDS-antiviral activity, and will provide the test results to Source Country Institution on a quarterly basis. Any extracts exhibiting significant activity will be further studied by bioassay-guided fractionation in order to isolate the pure compounds(s) responsible for the observed activity. Should the appropriate agency in [SCG or SCO] have any knowledge of the medicinal use of any plants, microbes and marine macro-organisms by the local population or traditional healers, this information will be used to guide the collection of plants, microbes or marine macro-organisms on a priority basis where possible. Details of the methods of administration (e.g., hot infusion, etc.) used by the traditional healers will be provided, where applicable, to enable suitable extracts to be made.
Purpose or background	DTP/NCI has an interest in investigating plants, microbes and marine macro-organisms from [Source Country], and wishes to collaborate with the SCG or SGO, as appropriate, in this investigation. The DTP/NCI will make sincere efforts to transfer knowledge, expertise, and technology related to drug discovery and development to the [appropriate Source Country Institution], subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology. The [SCG or SCO], in turn, desires to collaborate closely with the DTP/NCI in pursuit of the investigation of its

	plants, microbes and marine macro-organisms, subject to the conditions and stipulations of this agreement.
Contact details	National Cancer Institute, NCI-Technology Transfer Branch, National Cancer Institute at Frederick (NCI-Frederick), Fairview Center, Suite 500, 1003 - W. 7th Street, Frederick, MD 21701, United States of America. Telephone: 301-846-5465; Fax: 301-846-6820

(TTB Version 02/2002)

LETTER OF COLLECTION

The Developmental Therapeutics Program ("DTP"), Division of Cancer Treatment and Diagnosis ("DCTD"), National Cancer Institute ("NCI") is currently investigating plants, microbes, and marine macro-organisms as potential sources of novel anticancer and AIDS-antiviral drugs. The DTP is the drug discovery program of the NCI which is an Institute of the National Institutes of Health ("NIH"), an arm of the Department of Health and Human Services of the United States Government. While investigating the potential of natural products in drug discovery and development, NCI wishes to promote the conservation of biological diversity, and recognizes the need to compensate [Source Country, SC] organizations and peoples in the event of commercialization of a drug developed from an organism collected within their borders.

As part of the drug discovery program, DTP has contracts with various organizations for the collection of plants, microbes and marine macro-organisms worldwide. DTP has an interest in investigating plants, microbes and marine macro-organisms from [Source Country], and wishes to collaborate with the [Source Country Government ("SCG") or Source Country Organization(s) ("SGO")] as appropriate in this investigation. The collection of plants, microbes, and marine macro-organisms will be within the framework of the collection contract between the NCI and the NCI Contractor ("Contractor") which will collaborate with the appropriate agency in the [SCG or SCO]. The NCI will make sincere efforts to transfer knowledge, expertise, and technology related to drug discovery and development to the [appropriate Source Country Institution ("SCI")] in [Source Country] as the agent appointed by the [SCG or SCO], subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology. The [SCG or SCO], in turn, desires to collaborate closely with the DTP/NCI in pursuit of the investigation of

its plants, microbes and marine macro-organisms, subject to the conditions and stipulations of this agreement.

A. The role of DTP, DCTD, NCI in the collaboration will include the following:

1) DTP/NCI will screen the extracts of all plants, microbes and marine macro-organisms provided from [Source Country] for anticancer and AIDS-antiviral activity, and will provide the test results to [SCI] on a quarterly basis. Such results will be channeled via Contractor.

2) The test results will be kept confidential by all parties, with any publication delayed until DTP/NCI has an opportunity to file a patent application in the United States of America on any active agents isolated. Such application will be made according to the terms stated in Article 6.

3) Any extracts exhibiting significant activity will be further studied by bioassay-guided fractionation in order to isolate the pure compounds(s) responsible for the observed activity. Since the relevant bioassays are only available at DTP/NCI, such fractionation will be carried out in DTP/NCI laboratories. A suitably qualified scientist designated by [SCI] may participate in this process subject to the terms stated in Section A / Article 4. In addition, in the course of the contract period, DTP/NCI will assist the [SCO], in conjunction with [SCI], thereby assisting the [SC], to develop the capacity to undertake drug discovery and development, including capabilities for the screening and isolation of active compounds from plants, microbes and marine organisms.

4) Subject to the provision that suitable laboratory space and other necessary resources are available, DTP/NCI agrees to invite a senior technician or scientist designated by [SCI] to work in the laboratories of DTP/NCI or, if the parties agree, in laboratories using technology which would be useful in furthering work under this agreement. The duration of such a visit would not exceed one year except by prior agreement between [SCI] and DTP/NCI. The designated Guest Researcher will be subject to provisions usually governing Guest Researchers at NIH, except when carrying out research on materials provided through collections in [Source Country]. Salary and other conditions of exchange will be negotiated in good faith.

5) In the event of the isolation of a promising agent from a plant, microbe or marine macro-organism collected in [Source Country], further development of the agent will be undertaken by DTP/NCI in collaboration with [SCI]. Once an active agent is approved

by the DTP/NCI for preclinical development, [SCI] and the DTP/NCI will discuss participation by SCI scientists in the development of the specific agent.

The DTP/NCI will make a sincere effort to transfer any knowledge, expertise, and technology developed during such collaboration in the discovery and development process to [SCI], subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology.

6) DTP/NCI will, as appropriate, seek patent protection on all inventions developed under this agreement by DTP/NCI employees alone or by DTP/NCI and [SCG or SCO or SCI] employees jointly, and will seek appropriate protection abroad, including in [Source Country], if appropriate.

7) All licenses granted on any patents arising from this collaboration shall contain a clause referring to this agreement and shall indicate that the licensee has been apprized of this agreement.

8) Should the agent eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI, will require the successful licensee to negotiate and enter into agreement(s) with the [SCG] agency(ies) or [SCO] as appropriate. This agreement(s) will address the concern on the part of the [SCG or SCO] that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate.

9) Such terms shall apply equally to instances where an invention is directed to a direct isolate from a natural product material, a product structurally based upon an isolate from the natural product material, a synthetic material for which the natural product material provided a key development lead, or a method of synthesis or use of any aforementioned isolate, product or material; though the percentage of royalties negotiated as payment might vary depending upon the relationship of the marketed drug to the originally isolated product. It is understood that the eventual development of a drug to the stage of marketing is a long term process which may require 10-15 years.

10) In obtaining licensees, the DTP/NCI will require the license applicant to seek as its first source of supply the natural products from [Source Country]. If no appropriate licensee is found that will use natural products available from [Source Country], or if the [SCG] or [SCO] as appropriate, or its suppliers cannot provide adequate amounts of

raw materials at a mutually agreeable fair price, the licensee will be required to pay the [SCG] or [SCO] as appropriate, an amount of money (to be negotiated) to be used for expenses associated with cultivation of medicinal plant, microbe or marine macro-organism species that are endangered by deforestation, or for other appropriate conservation measures. These terms will also apply in the event that the licensee begins to market a synthetic material for which a material from [Source Country] provided a key development lead.

11) Section 10 shall not apply to organisms which are freely available from different countries (i.e., common weeds, agricultural crops, ornamental plants, fouling organisms) unless information indicating a particular use of the organism (e.g., medicinal, pesticidal) was provided by local residents to guide the collection of such an organism from [Source Country], or unless other justification acceptable to both the [SCG or SCO] and the DTP/NCI is provided. In the case where an organism is freely available from different countries, but a phenotype producing an active agent is found only in [Source Country], Article 10 shall apply.

12) DTP/NCI will test any pure compounds submitted by the [SCG or SCO] and [SCI] scientists for anti-tumor and anti HIV/AIDS activity, provided such compounds have not been tested previously in the DTP/NCI screens. If significant anti-tumor or anti HIV/AIDS activity is detected, further development of the compound and investigation of patent rights will, as appropriate, be undertaken by DTP/NCI in consultation with [SCI] and the [SCG or SCO].

Should an agent derived from the compound eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI will require the successful licensee to negotiate and enter into agreement(s) with the appropriate [SCG agency(ies) or SCO]. This agreement will address the concern on the part of the [SCG or SCO] that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate.

13) DTP/NCI may send selected samples to other organizations for investigation of their anti-cancer, anti-HIV or other therapeutic potential. Such samples will be restricted to those collected by NCI contractors unless specifically authorized by the [SCG or SCO]. Any organization receiving samples must agree to compensate the [SCG or SCO] and individuals, as appropriate, in the same fashion as described in Articles 8-10 above, notwithstanding anything to the contrary in Section 11.

B. The role of the Source Country Government ("SCG") or Source Country Organization(s) ("SCO") in the collaboration will include the following:

1) The appropriate agency in [SCG or SCO] will collaborate with Contractor in the collection of plants, microbes and marine macro-organisms, and will work with Contractor to arrange the necessary permits to ensure the timely collection and export of materials to DTP/NCI.

2) Should the appropriate agency in [SCG or SCO] have any knowledge of the medicinal use of any plants, microbes and marine macro-organisms by the local population or traditional healers, this information will be used to guide the collection of plants, microbes or marine macro-organisms on a priority basis where possible. Details of the methods of administration (e.g., hot infusion, etc.) used by the traditional healers will be provided where applicable to enable suitable extracts to be made. All such information will be kept confidential by DTP/NCI until both parties agree to publication.

The permission of the traditional healer or community will be sought before publication of their information, and proper acknowledgment will be made of their contribution.

3) The appropriate agency in [SCG or SCO] and Contractor will collaborate in the provision of further quantities of active raw material if required for development studies.

4) In the event of large amounts of raw material being required for production, the appropriate agency of the [SCG or SCO] and Contractor will investigate the mass propagation of the material in [Source Country]. Consideration should also be given to sustainable harvest of the material while conserving the biological diversity of the region, and involvement of the local population in the planning and implementation stages.

5) [SCG or SCG] and SCI scientists and their collaborators may screen additional samples of the same raw materials for other biological activities and develop them for such purposes independently of this agreement.

This agreement shall be valid as of the date of the final authorized signature below for an initial period of five (5) years, after which it can be renewed by mutual agreement. It may be amended at any time subject to the written agreement of both parties. Copies of such amendments will be kept on file at both of the addresses indicated below.

For the National Cancer Institute:	For [SCI] or [SCO]:
_____	_____
Andrew C. von Eschenbach, M.D. Director, National Cancer Institute	Name (typed): Title:
_____	_____
Date	Date

Mailing and contact address:

Technology Transfer Branch
National Cancer Institute at Frederick
Fairview Center, Suite 502
1003 - W. 7th Street
Frederick, Maryland 21701-8512
United States of America
Telephone: 301-846-5465
Facsimile: 301-846-6820

NIH の遺伝資源用 Material Transfer Agreement (MTA)

Model Agreement First Approved: May 22, 1989
Last Revised and Approved by TTB/NCI and DCTD/NCI: October 29 , 1999

Natural Products Branch
Developmental Therapeutics Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute
National Institutes of Health

NATURAL PRODUCTS REPOSITORY MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement ("MTA") has been adopted for use by the National Institutes of Health ("NIH") and revised for use in the Natural Products Branch ("NPB") of the Developmental Therapeutics Program (DTP), of the Division of Cancer Treatment and Diagnosis ("DCTD"), of the National Cancer Institute ("NCI") of the NIH for all transfers of research materials ("Research Material") from the Natural Products Repository ("NPR") of NPB, DTP, DCTD, NCI.

The NPR represents a resource of natural products (e.g., plant extracts, microbial cultures, etc.) which are being used for the discovery and development of new agents for the treatment and prevention of cancer and AIDS. These Research Materials have been collected from one or more Source Countries, generally in collaboration with one or more Source Country Organizations. ("Source Country Organization" or "SCO" is defined as a governmental entity of a country from which the Research Material was obtained or an appropriate organization affiliated with the Source Country with authority to provide the Research Material to NCI.) NCI wishes to promote the use of this national resource by other organizations involved in the discovery of bioactive agents of relevance to the NCI mission, and will provide limited quantities of Research Materials from the NPR to selected qualified research organizations for such purposes, under the selection criteria and procedures set forth in Appendix A.

This MTA specifies the conditions under which NCI will transfer samples to successful applicant investigators. In the event an applicant is successful, this MTA represents the terms of agreement between NCI and the applicant investigator's institution [hereinafter referred to as "Recipient," except that "Recipient" will refer to the investigator as an individual if he or she is unaffiliated with an institution].

Specifically:

1. NCI shall disclose to Recipient Confidential Information on the Research Materials currently available from the NPR solely for the purpose of and in sufficient detail to enable Recipient to identify and select specific Research Materials for evaluation as described in Recipient's proposal to NPB, DTP and approved by the DTP Committee on Natural Products Repository Access on _____.

Alternatively, Recipient may specify immediately below the types of Research Materials it would like to access from the NPB:

However, Recipient will not have access to Research Materials in the Active Repository (i.e., materials that are or recently have been the subject of investigation by NCI scientists), nor will it be informed about what materials are in the Active Repository, unless Recipient agrees to the special terms appearing on Page 6 of this Agreement.

Recipient agrees to accept the Confidential Information and employ all reasonable efforts to maintain the Confidential Information secret and confidential, such efforts to be no less than the degree of care employed by Recipient to preserve and safeguard Recipient's own confidential information. The Confidential Information shall not be disclosed, revealed or given to anyone except employees of Recipient who shall have a need to have Confidential Information in connection with Recipient's evaluation, and who have entered into a secrecy agreement with Recipient (or are covered by a secrecy obligation to Recipient) under which such employees are required to maintain confidential and secure the proprietary information of Recipient. Furthermore, such employees shall be advised by Recipient of the confidential nature of the Confidential Information and of their obligation to treat the Confidential Information accordingly.

It is hereby acknowledged by NCI that Recipient shall incur no liability merely for examining and considering the Confidential Information; however, Recipient agrees that it will not use the Confidential Information for any purpose except as set forth herein.

2. NCI agrees to transfer to Recipient for evaluation specific crude extracts listed in the Confidential Information, upon request by Recipient and approval by NPB, DTP. An electronic record of the specific extracts provided will be kept by the NPB and will be updated as Research Materials are provided to Recipient. This electronic record will serve as an appendix to this agreement. A written copy of this record will be provided on a periodic basis or upon request to the Recipient.

3. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS. This Research Material will only be used for research purposes by Recipient under suitable containment conditions. Exchange of samples among collaborating organizations or individuals not party to this MTA may occur only upon execution of a copy of this MTA by each such collaborator. This Research Material will not be used for commercial purposes such as production or sale. A commercialization license may be required for commercial use of the Research Material. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

4. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge the contribution of NCI, as well as the SCO and any other appropriate organizations or individuals as identified by NCI, unless requested otherwise. To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any and all of NCI's written information about this Research Material that is stamped "CONFIDENTIAL" except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Recipient may publish or otherwise publicly disclose the results of the Research Project. However, if NCI has given CONFIDENTIAL information to Recipient, such publication or public disclosure may be made only after the SCO has had thirty (30) days following notification by the NPB to review the proposed disclosure, except in the event that a shortened time period is required pursuant to a court order or request under the

Freedom of Information Act, 5 U.S.C. 522. Recipient agrees to inform the NPB, under reasonable reporting requirements, of the intent, progress, results and additional research plans for the use of the Research Material. NCI agrees to reciprocally maintain information Recipient identifies as "CONFIDENTIAL" under the terms set forth above.

5. This Research Material represents a significant investment on the part of NCI and is considered proprietary to NCI. Recipient agrees to retain control over this Research Material, and further agrees not to transfer the Research Material to others not under Recipient's supervision without advance written approval of NCI. The execution by others of an MTA such as this, as described in Article 3 above, would constitute one form of such approval. NCI reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Project is completed, or three (3) years have elapsed, whichever occurs last, the Research Material will be destroyed or disposed of as mutually agreed by NCI and Recipient.

6. This Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NCI makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.

7. Recipient agrees to pay all reasonable costs for the preparation, handling and shipment of this Research Material to Recipient. Further, Recipient agrees that all samples of Research Material will be provided contingent on the availability of a sufficient supply of Research Material, but in no case will samples be provided that adversely affect the research programs of NCI.

8. NCI shall retain title to the Research Material, per se, and any patent or other intellectual property rights in inventions by its employees in the course of the Research project. Furthermore, Recipient agrees that any intellectual property rights in inventions made by the employees, agents or contractors of the Recipient will vest by operation of inventorship as determined under appropriate patent statutes in the controlling jurisdiction(s). Recipient agrees not to claim, infer, or imply Government endorsement of the Research Project, the institution or personnel conducting the Research Project, or any resulting commercial product(s). Recipient agrees to hold the

United States harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of Recipient's use for any purpose of the Research Material.

9. Recipient acknowledges that NCI may have obtained the Research Materials from the SCO under a Letter of Collection ("LOC") agreement stipulating that NIH will require any commercial licensee of an invention by NCI personnel derived from the Research Material (whether the invention is directed to a direct isolate from the Research Material, a product structurally based upon an isolate from the Research Material, a synthetic material for which the Research Material provided a key development lead, or a method of synthesis or use of any aforementioned isolate, product or material) to enter into an agreement that addresses the mutual concerns of NIH's licensee and SCO, respectively.

Even if the Research Materials were not obtained under such an LOC agreement, as an agency of the U.S. Government, NCI complies with the U.S. Government's policy to follow the principles articulated in the United Nations Convention on Biological Diversity ("U.N. CBD"). The U.N. CBD calls for "sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the [source country] providing such resources." (U.N. CBD; Article 15.7)

In order to abide by these principles and address the interests of SCO, Recipient further agrees that, should an invention derived from the Research Material eventually be developed and marketed by the Recipient, or licensed by Recipient to a company or other institution for development and commercialization (whether the invention is directed to a direct isolate from the Research Material, a product structurally based upon an isolate from the Research Material, a synthetic material for which the Research Material provided a key development lead, or a method of synthesis or use of any aforementioned isolate, product or material), Recipient or Recipient's Licensee(s) will negotiate and enter into an agreement with the appropriate SCO. This agreement between the Recipient and/or Recipient's Licensee(s) and SCO will address the mutual concerns of both parties. Recipient agrees that negotiations between either Recipient or Recipient's Licensee(s) and the SCO must commence prior to the start of clinical development studies that are conducted, directed or sponsored by either Recipient or Recipient's Licensee(s). Negotiations must be completed and an agreement executed

prior to the commercial sale of an agent structurally based or isolated from the Research Material. This agreement relating to the agent must be binding upon SCO, Recipient and any Licensee(s) or assignees of Recipient with respect to any intellectual property rights relating to the agent.

Recipient will seek to utilize the Source Country as its first source of supply and/or cultivation for raw (natural product) materials required for the manufacture of an agent (regardless of whether the agent is an isolated natural product or is structurally based thereon) if such material can be made available in quantities and quality sufficient for use by the Recipient at a mutually agreeable fair price. If such material must be cultivated, recipient agrees to seek to utilize Source Country as its first source of such cultivation efforts.

10. In addition to the reporting requirements under Article 4, Recipient will provide screening results on the Research Material to NPB, DTP. Following removal of identified proprietary information (jointly defined by Recipient and DTP/NCI), DTP/NCI will provide summary screening data to the SCO.

11. NCI can promise an option to license intellectual property rights only under a Cooperative Research and Development Agreement (CRADA). If Recipient desires prospective license rights to inventions derived from Research Material made in whole or part by NCI employees, a formal CRADA must be negotiated. For general inquiries regarding CRADAs or NCI technology transfer policies, contact the NCI Technology Transfer Branch at (301)-846-5465.

12. This MTA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.

13. This Materials Transfer Agreement between NCI and the Recipient will be effective when signed by all parties. By signing this MTA, the Recipient acknowledges that it has received and read a copy of the policy statement on Distribution of Materials from the Natural Products Repository, which is attached as Appendix A.

14. The provisions of this Agreement are severable. If any item or provision of this Agreement shall to any extent be invalid or unenforceable, the remainder of this Agreement shall not be affected thereby, and each item and provision of this Agreement

shall be valid and shall be enforced to the fullest extent permitted by law. The undersigned expressly certifies or affirms that the contents of any statements made or reflected in this document are truthful and accurate.

FOR RECIPIENT:

Date: _____ _____

Applicant Investigator's Signature / Title / Program

Date: _____ _____

Signature for Recipient's Authorizing Official

Name (Type or Print):

Title (Type or Print):

Recipient's Address for Correspondence Related to this Agreement to:

_____

_____ Tel:_____

_____ Fax:_____

FOR THE NATIONAL CANCER INSTITUTE:

Date: _____ _____

Jerry Collins, Ph.D.

Associate Director, Developmental Therapeutics Program, DCTD

Date: _____ _____

Bjarne Gabrielsen, Ph.D., Senior Advisor, Drug Discovery / Development

Technology Transfer Branch, NCI

Address correspondence related to this Agreement to:

NCI-Technology Transfer Branch
National Cancer Institute at Frederick (NCI-Frederick)
Fairview Center, Suite 500
1003 - W. 7th Street
Frederick, MD 21701

telephone: 301-846-5465
fax: 301-846-6820

SPECIAL ADDITIONAL PROVISIONS THAT APPLY TO SAMPLES FROM THE ACTIVE REPOSITORY

In the case of applications for access to Research Material from the Active Repository (i.e., materials that are or recently have been the subject of investigation by NCI scientists), Recipient recognizes that such materials are of current interest to NCI and that there has been intellectual input by NCI scientists into the screening, and in many cases further analysis and development, of such materials. Recipient therefore agrees that the use of the Research Material constitutes a form of collaboration with NCI's Natural Products Branch or other designated NCI facility, as appropriate. Recipient further agrees to comply with the provisions set forth hereunder, so that the isolation, purification and testing of the Research Material will be closely coordinated with NCI's efforts to ensure that pure isolates from such Research Material may be further developed in an efficient manner and in cooperation with the NCI.

In particular, Recipient agrees to report in a timely fashion to NCI the identity and nature of any isolates, including identified compounds or combinations of compounds, derived from the Research Material; as well as any processes for making or using such isolates. In addition, Recipient agrees to report to the NCI Technology Transfer Branch (see the address on the Signature Page) Recipient's intention to file patent applications on any inventions developed from the use of Research Material and to negotiate in good faith a Confidentiality Disclosure Agreement with NCI under which NCI/DTP and Recipient will exchange information regarding their respective research and development efforts to ensure that Recipient's and NCI's interests in Research Material may be respectively, and where appropriate jointly, protected.

Recipient understands that a limited number of samples from the Active Repository (generally no more than twenty) can be made available at any one time under any single Agreement. Recipient agrees that once it has completed analysis of a sample, it will return any and all remaining sample to NPB, DTP. At any time following Recipient's receipt of the first group of samples, DTP has the right to make access to additional samples from DTP repositories contingent upon Recipient's entering into a Cooperative Research and Development Agreement (CRADA) with NCI to ensure that Recipient's and NCI's respective development efforts are coordinated.

Recipient's signatures on below signify agreement to these special provisions regarding

access to Research Material from the Active Repository. Access to Research Material from the Active Repository will not be granted without such agreement.

Signature of Recipient's investigator signifying agreement to the Special Provisions governing access to samples from the Active Repository:

_____ Date: _____

Signature of Recipient's authorizing official signifying agreement to the Special Provisions governing access to samples from the Active Repository:

_____ Date: _____

Original, December 13,1991
Last Revised by DTP/NCI October 29, 1999

Appendix A

POLICY FOR THE DISTRIBUTION OF MATERIALS FROM THE NATURAL PRODUCTS REPOSITORY

The Natural Products Repository (NPR) of the National Cancer Institute's (NCI) Developmental Therapeutics Program (DTP) represents a unique resource in terms of both the magnitude and diversity of materials that might be utilized for the discovery and development of new agents for cancer, HIV/AIDS, and other diseases, as well as for other meritorious research endeavors. As a national resource, it is incumbent on the NCI to assure that it is utilized to the greatest extent for the public good.

Two programs for access to the NPR have been established:

- The Open Repository Program.

- The Active Repository Program.

OPEN REPOSITORY PROGRAM

This program was established in 1992 to enable the extramural community to investigate NPR materials, not currently under active investigation at the NCI, as potential sources of agents for the treatment of cancer, AIDS, opportunistic infections, and diseases of concern to the Countries of Origin of the materials. In 1999, the scope of investigation was expanded to include all human diseases.

Distribution of Materials:

- Vialed Samples: Samples (25 mg), identified by a code number and by taxonomy to family level, may be shipped to a recipient at a maximum rate of 500 per month (this rate may be accelerated if a formal CRADA is in place). Particular genera and/or species within a family, or samples from specified Countries of Origin, may be included or excluded, as far as possible, from shipments if requested

- Plated Samples: Samples may also be shipped to a recipient in 96-well polypropylene (15mg or 500ug per well) or polystyrene (50ug per well) plates; there is no restriction on the rate of shipment of plated samples. No initial exclusivity will be granted to the extracts, nor will any information other than the type and source of the extracts on a particular plate be provided (i. e. plate # contains 88 organic plant extracts at 50ug per well in lanes 2 through 12). Plates may also contain samples from the Active Repository Program; such extracts will only be available to investigators qualified for access to the Active Repository Program. Identical plates may be sent to multiple investigators.

- An exclusivity period of 3 months is granted for testing of the materials, after which the test results are submitted to the DTP Natural Products Branch (NPB).

- On identification of active extracts, investigators will communicate with NPB directly by e-mail or fax, and will be informed whether or not the active materials are available.

- Investigators will have active samples reserved for further investigation on a first-come first-served basis. Where more than one investigator observes activity for a particular extract, it will be reserved for the first investigator to report activity, and a waiting list of other interested investigators will be established.

- Extracts will not be available if they are under active study (on reserve) in either the Open Repository Program (maximum of 6 months exclusivity) or Active Repository Program (up to 15 months exclusivity with the possibility of extension, if necessary).

- Once the relevant extract is released by the first investigator, it will be shipped to the next in line on the waiting list.

- A further supply of any active materials (75-100 mg), together with the rest of the taxonomy and relevant collection data, are provided.

- A further 3 months exclusivity is granted to permit secondary testing and/or

initial isolation of the active agents. At the end of this time the recipient will inform NPB of its discoveries and its level of interest.

- The maximum period of exclusivity on any extract is 6 months.

- At the end of the 6 month period from the initial receipt of the material, NPB will inform the Countries of Origin of the materials of the results obtained, using language agreed to in advance by the recipient.

- The Countries of Origin will be given the name of the recipient organization, and will be informed that the organization will contact them if further material is required. Acquisition of further material will normally be the responsibility of the recipient organization working through the original collector (if possible) and the relevant Source Country permitting agency.

- Since it is the responsibility of the NCI to ensure that the conditions of the *Material Transfer Agreement* (MTA) are maintained during this and subsequent stages of development, NPB will maintain interaction with the recipient organization and the Countries of Origin.

Requests for Access

Requests for NPR materials wilt be accepted from research organizations and individual investigators in the form of a brief proposal (up to 5 pages) formatted as follows:

- Introduction.

- Research Hypothesis.

- Screening Process, together with description of characteristics of the screen.

- Personnel.

- Organizational Research Capabilities.

Requests will normally be reviewed by staff from the NCI Division of Cancer Treatment and Diagnosis (DCTD) appointed by the Director, DCTD. Ad hoc members from outside the Division, Institute, or NIH may be appointed as needed, while ensuring appropriate confidentiality of information provided in the proposal.

The review will consider primarily the scientific merit of the proposal related to the screening target for
drug discovery, and the applicant's chemical and pharmaceutical expertise for adequate follow-up on the natural products supplied from the NPR. Although preference will be given to proposals related to cancer or AIDS, other areas of research will be given consideration.

The Committee to review applications for access to the Natural Products Repository will accept and review proposals on a continuing basis. This schedule is subject to change depending on the volume of applications.

Conditions of Access

The staff of the Natural Products Branch will be administratively responsible for the operation of this program. Successful applicants will subsequently deal directly with the Branch to request material and report scientific results.

Organizations and 'individual investigators whose applications are approved will be provided selected samples under the terms of a Material Transfer Agreement (to which this Policy Statement is attached), which has been modified from the standard Public Health Service (PHS) agreement to meet the specific needs of this program. Important aspects of this agreement are:

- Recipients must agree to protect the interests of the Countries of Origin providing the materials to NCI.

- The NCI will retain ownership of the material per se. Such ownership is separate from intellectual property rights.

- The recipient will pay the "out-of-pocket" costs of preparing and shipping samples.

- In no case will a sample be provided that depletes the supply of that material or otherwise affects adversely NCI's own efforts.

- Unused samples will be disposed of in a manner to be agreed on by both parties.

- A reporting procedure will be established to assure that NCI is kept informed of the usage of Research Materials. To this end, recipients are encouraged to contact the NPB as early as possible once a particular extract has proven to be of interest in order that suitable arrangements for further development may be agreed upon by all parties. These may include full taxonomic identification; provision of more extracted Research Material; aid in obtaining raw material via the then current Collection Contractors; or the negotiation of a formal Cooperative Research and Development Agreement (CRADA).

- Research results derived from this Research Material will be transmitted in a timely manner to the NCI.

    - A summary of the screening results relating to the Research Material and any purified natural products will be provided to the relevant organizations in the Countries of Origin.

    - Safeguards will be installed to prevent disclosure of proprietary information during this interchange.

    - As part of this interchange of information, if a research organization has been identified within the Country of Origin that is actively pursuing studies in the relevant scientific area, then the recipient will be informed with the aim of facilitating collaborative studies.

- All test information from NCI that is provided to recipient, collector, and the Country of Origin government or an appropriate organization within the Country of Origin is to be maintained as “CONFIDENTIAL” with any publication delayed until DTP authorizes release to outside parties.

- The NCI will not grant unlimited access to Research Materials within the repository. The selection of samples will be determined by the NCI after discussion with the recipient, and the size of samples will be limited to that required for primary and limited secondary testing in the recipient's screens.

- Large amounts of raw material required for follow-up isolation and development of active agents will generally be obtained by recipients at their own expense and in accordance with established agreements among NCI, its collecting agents and the Source Country Organization. In specific cases, however the NCI may agree to participate with the investigator(s) in the recollection process to procure additional raw and/or Research Material if the initial findings are of substantial scientific interest to the program.

Further technical information may be obtained from:

Dr. David Newman
Chief, Natural Products Branch
NCI-FCRDC
Fairview Center, Room 206
P. 0. Box B
Frederick, MD 21702-1201

Phone:301-846-5387
Fax:301-846-6178
Email: newmand@mail.nih.gov

Requests for samples may be transmitted electronically to:

Mrs Erma Brown at the address and phone/fax numbers given above, or by Email at

browne@dtpepn.nci.nih.gov

Requests must be copied to Dr. Newman at:

newmand@mail.nih.gov

ACTIVE REPOSITORY PROGRAM

This program has been established to permit qualified U.S. investigators access to materials active in the 60 cell line anti-tumor screen, in addition to those falling into the Open Repository Program. As of Febraury, 1999, over 3,000 samples have been designated as active.

Qualifications for Access

- U. S.-based investigators whose screening activities have been peer-reviewed by suitable bodies (e.g., U. S. Government funding agencies, the American Cancer Society and other comparable U. S. funding organizations). Such investigators will provide current grant number(s).

- U. S. chartered organizations whose screening activities have not been peer-reviewed. Such organizations will submit short proposals for review as discussed under "Requests for Access" in the section on the Open Repository Program.

- Organizations based in Countries of Origin that have participated in NCI collection programs. Such organizations have access to extracts of organisms collected in their own countries.

All investigators and organizations requesting access to the Active Repository Program will be asked to provide the following information:

- A brief description of their assays and their relevance to cancer.

- A description of the expertise in chemistry available for bioassay-guided isolation studies.

- The types of extracts desired for testing (one or more of marine or terrestrial plants or marine invertebrates).

Distribution of Materials

- Upon signing of the special terms appearing on page 6 of the Material Transfer Agreement (to which this policy statement is attached), NPB will provide investigators with electronic media containing details of all materials available (full taxonomy and anti-cancer screening data sets composed of single- and multi-dose tests, together with mean graphs).

- Investigators may choose up to 20 samples for further study.

- 25 mg of each selected sample will be provided for investigators to determine if their assays will detect the activities.

- Plated Samples: Investigators receiving plated samples through the Open Repository Program may identify extracts restricted to the Active Repository Program. Such extracts may be made available to the investigators providing they qualify for access to the Active Repository, and subject to the 20 sample restriction mentioned above.

- On identification of active extracts, investigators will communicate with NPB directly by e-mail or fax, and will be informed whether or not the active materials are available.

- Investigators will have active samples reserved for further investigation on a first-come first-served basis. Where more than one investigator observes activity for a particular extract, it will be reserved for the first investigator to report activity, and a waiting list of other interested investigators will be established.

- A three month exclusivity period will be granted from the date of receipt of the samples during which time the investigators will inform NPB whether their assays are effective.

- Materials for further investigation may be obtained as follows:

    - Grantees, non-profit organizations and small businesses (that meet

SBIR criteria): NPB will provide further materials in negotiated amounts.

- For-profit organizations not qualifying as small businesses under SBIR regulations will be responsible for the acquisition of further material, working in collaboration with the original collector (if possible), and the Country of Origin as stipulated in Article 9 of the MTA.

- A further exclusivity period of one year from the time of receipt of the second amount of material will be given to perform bioassay-guided isolation of the active agents. If necessary this period may be extended after review of progress by NPB and the investigator.

- The 20 samples are on a rotating basis. When the investigator decide not pursue further research on a sample, or identifies the active agent(s) in a sample, the remainder of that particular sample will be returned to NPB within five working days of reclassification.

- For each sample reclassified as being of no further interest to the investigator, one new sample may be requested. No more than 20 samples from the Active Repository Program may be held at one time.

- NCI will be kept informed of the progress of the investigations, and will help in the development of any agents meeting the approval criteria of the DCTD Drug Development Committee.

- Since it is the responsibility of the NCI to see that the conditions of the MTA are maintained during this and subsequent stages of development, NPB will maintain interaction with the investigators and the relevant Countries of Origin.

Conditions of Access

The same conditions of access as apply to the Open Repository Program (vide infra) generally apply to the Active Repository Program, except for differences specified under the Distribution of Materials. Further technical information may be obtained from:

Dr. David Newman
Chief, Natural Products Branch
NCI-FCRDC
Fairview Center, Room 206
P. 0. Box B
Frederick, MD 21702-1201

Phone:301-846-5387
Fax:301-846-6178
Email: newmand@mail.nih.gov

Test results and requests for samples may be submitted to:

Mrs Erma Brown at the address and phone/fax numbers given above, or by Email at

browne@dtpepn.nci.nih.gov

Requests must be copied to Dr. Newman at: newmand@mail.nih.gov

Plant Exchange Office
USDA/ARS, Beltsville, Maryland

米国農務省の NPGS CODE OF CONDUCT FOR FOREIGN PLANT EXPLORATIONS

This code of conduct is intended to guide NPGS plant explorers when collecting germplasm in foreign countries. Explorations are the main means of acquiring plant genetic resources that are not available in national or international collections. The successful implementation of a plant exploration in a foreign country requires careful consideration of scientific, political, and cultural matters. A plant explorer on an NPGS-sponsored exploration must respect the laws, customs, and environment of the host country. NPGS plant explorations abide by the principle of national sovereignty

over plant genetic resources recognized in the UNEP Convention on Biological Diversity (CBD) and the UN FAO International Treaty on Plant Genetic Resources for Food and Agriculture. Accordingly, access to genetic resources is subject to prior informed consent of the national authority in the host country and shall be on mutually agreed terms. The NPGS process for obtaining access to genetic resources and identifying benefit sharing follows the recommendations in "The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization" (http://www.biodiv.org/decisions/default.aspx?m=cop-06&d=24), a document developed by the Conference of the Parties to the CBD.

The process of executing an NPGS- supported plant exploration can be broken down into several elements: 1) Planning and preparing an exploration proposal, 2) Pre-trip preparation following funding, 3) Pre-travel preparation in host country prior to collecting, 4) Fieldwork and collecting, 5) Post-fieldwork sorting and cleanup at host institution, 6) Follow-up upon return to home country. The requirements for completing each of these phases following legal, ethical, and conservation standards are presented below.

PLANNING AND PREPARING AN EXPLORATION PROPOSAL

A plant exploration in a foreign country must include a host country collaborator. The ideal collaborator is a scientist already working with the target crop or crop group who would also benefit from the collection of the genetic resources. Collaboration with the national genetic resources programs in host countries is strongly encouraged. Host country scientists must be included in the planning process. Therefore, contact your potential host country collaborators as early as possible when planning an expedition.

Collectors are required to comply with all host country rules and regulations on access to genetic resources. Obtain prior informed consent from host country authorities as early as possible in the planning process. Your host may be able to assist you with application for access permission. However, your host may not be aware of the national requirement to obtain access permission and may only know about the need for local permissions. The Plant Exchange Office can assist with communication with host country authorities and establishing the terms of access

agreements. This process should be started well in advance of the exploration.

Determine how your proposed expedition may benefit national programs in the host country. Typical benefits include training in germplasm exploration methods, establishment of national germplasm collections with backups in international genebanks, transfer of information and technology, and collaboration in publication of research results. Additional non-monetary benefits may be provided based on the specific needs of the host country.

Determine in advance where collections will ultimately be deposited and who will have access to them. All germplasm collected on NPGS explorations will be shared between the appropriate host country institutions and the NPGS. Germplasm deposited in the NPGS will be curated on behalf of the U.S. Government and become available to bona fide users, domestic or foreign. Germplasm collected on NPGS-supported explorations is considered in the public domain and cannot be patented by the U.S. Government. While the NPGS will notify recipients of any restrictions on particular accessions, it does not have control over how the end user might utilize germplasm. Host countries may request certain restrictions or requirements concerning intellectual property rights. The Plant Exchange Office reviews requested restrictions to ensure agreement with U.S. government policy. All potential restrictions must be clarified in advance of any collecting.

Determine who will provide transportation and how costs will be shared for the exploration. If host country institutions provide a vehicle, it is customary for visitors to cover all operating expenses, maintenance, and most repairs (except perhaps full cost of major repairs). In addition, it is not unreasonable for hosts to require reimbursement in the form of a rental agreement. This should be agreed to in advance to avoid later misunderstanding. Besides expenses, host institutions may require that U.S. collaborators provide per diem for host collaborators.

When a proposal is submitted to the NPGS, written proof of host country interest and collaboration is required, both from collaborating scientists and their institutions. Collaborators should be notified when the proposal is submitted to the NPGS and be given a copy of the final proposal.

PRE-TRIP PREPARATIONS

Notify collaborators upon NPGS approval of proposal.

Prepare a list of equipment and supplies that must be purchased and carried to host country. Unless prior arrangements have been made, do not assume that host institutions will be able to supply expeditions with plant presses, corrugates, paper bags, envelopes, field labels, etc. Find out in advance if you can bring hard- to-get supplies or materials needed by host country collaborators.

Ask host country scientists if they are interested in receiving germplasm that can be provided from the NPGS collections. If so, arrange to carry the germplasm with you. Obtain any necessary import permits and phytosanitary certificates before departure.

Visiting scientists should offer to present guest lectures at host institutions. They should travel with one or more lectures on activities of their home institution or their current research. PowerPoint presentations or other visual aids are useful. Scientific literature and a scientist's reprints are often the most valued gifts that can be left behind in host countries. Difficult to obtain publications and books are usually welcome contributions to host institutions. Ask in advance what literature is most needed.

TRAVEL PREPARATION IN HOST COUNTRY

Meet all collaborators, hosts, and essential government officials. Visits to government offices are important and appropriate.

Present seminars, share research activities and talk to graduate students.

Discuss with host colleagues the final responsibilities for trip expenses, itinerary, and how germplasm will be collected and divided.

FIELDWORK AND COLLECTING

Approach all plant collecting with a conservation ethic in mind. Do not collect so as to endanger any natural plant population. Leave sufficient material behind so that a plant population can naturally regenerate. For cultivated material,

acknowledge the contribution of germplasm shared by farmers.

Respect the local farmers, who are the trustees of local genetic material, for their knowledge and continued preservation of the crop landraces they grow. Work with them; in most cases they have extremely useful information to share about how and why certain plants are grown.

Do not expect your hosts to work on national holidays. Respect their political or religious holidays as well as any important religious observances.

Follow your hosts' lead in observing local customs and behavior. While your preferred field attire may seem entirely appropriate in your home country, it may not be appropriate in foreign settings.

Be respectful when photographing people and sensitive sites. Always ask permission to take photographs of people. It is appropriate for people to ask for duplicates of photographs that you take of them. An instant camera that produces photos immediately can be extremely useful. Do not take photos that would be embarrassing to your hosts.

Avoid "pushing" your hosts to travel to areas where they feel uncomfortable. There may be good reasons for their reluctance to venture into areas of local unrest, even though desired germplasm is known to occur there.

Consider the need for voucher herbarium specimens for study by specialists in the NPGS and host countries. Wild species in particular should be documented by herbarium specimens and duplicates offered to herbaria in the host country. Photos documenting plant habit and habitat provide a valuable reference.

Take detailed notes and collecting information. Your hosts may want to take their own notes, but your data and notes should still be shared with them.

Approach foreign travel as a learning experience, keeping an open mind. There is usually a reason for everything. Do not criticize what may seem unusual or unnecessary by your standards.

A successful expedition requires that foreign and host scientists work together. Sharing of expertise and knowledge while undertaking fieldwork is essential.

POST-FIELDWORK CLEANUP

Equally divide all collected germplasm and herbarium specimens, unless otherwise prearranged. If only three seeds are collected, two go to the host institution and one to the NPGS. An alternate arrangement, which may be better under some circumstances, is for the host institution to grow out all of the seed and later ship a modest sample to the NPGS.

Obtain a phytosanitary certificate from the host country regulatory office. It is not unreasonable for a host to require a few days to help procure the necessary phytosanitary certificates or other export permits prior to departure.

Leave a photocopy of your field notes with the host institution. Specify when you expect to send typed notes or labels. Some institutions appreciate copies on diskette.

Draft at least a short joint trip report including all collaborators prior to departing the host country.

Discuss with your hosts how they can take part in publishing results from the field collecting. They should be involved in publications that result from fieldwork in which they participated.

Be sensitive to host country constraints to germplasm exchange! Host institutions may not be able to release germplasm prior to your departure. Respect their requirements. Your hosts may be following government directives on policy over which they have no control. Do not place your hosts in an embarrassing situation.

FOLLOW-UP UPON RETURN

Promptly send a complete trip report and field collection data in final form to your collaborators, the NPGS site where the germplasm will be deposited, and the Plant Exchange Office. Acknowledge all host country participants as collectors in report and field collection data.

Arrange for shipment of any NPGS germplasm requested by your collaborators.

Maintain contacts with collaborators through timely correspondence.

Promptly follow through with non-monetary benefit sharing provisions of access agreements.

Acknowledge all exploration participants in presentations and papers.

Send letters to collaborators, hosts and government officials acknowledging their assistance. Duplicates of select photographs taken on the trip are always appreciated.

Provide the host country with a list of assigned identification numbers when collections have been incorporated into the NPGS.

Do not discuss problems encountered on a trip any more widely than is necessary.

Plant Exchange Office
National Germplasm Resources Laboratory
Rm. 329, Bldg. 003, BARC-West
Beltsville, MD 20705-2350
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Email: jjschnitlzer@ucdavis.edu
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INTRODUCTION
This Web Resource is intended to guide the on-line reader through the vast field of literature on the subject of bioprospecting. While this outline only represents a fraction of what is on-line, the resources listed below represent a balanced view of the subject matter, while taking into account the diverse viewpoints and debate on the subject of bioprospecting itself. Additional links are also provided for further reference and critical evaluation of the current activities and debates on this multi-faceted, ever-evolving and highly relevant topic in today's global forum.
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3.5.2 BIO "Biotechnology's Foreign Policy", Carl B. Feldbaum, President Biotechnology Industry Organization June 10, 2002

3.6 Practical Pointers for Industry:

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4.1 Interest-based Negotiation

4.2 Issues in multi-party complex negotiations

4.3 Possible role of mediation/multi-party facilitation in the agreement process

4.4 Prior Informed Consent Processes

4.4.1 “Politics, culture and governance in the development of prior informed consent and negotiated agreements with indigenous communities”

4.4.2 “The Philippines: A Bridle on Bioprospecting?” by Oscar B. Zamora

4.4.3 “Developing a Regime to Protect Indigenous Traditional Biodiversity - Related Knowledge” by Henrietta Fourmile-Marrie

4.4.4 “Ethics and Practice in Ethnobiology and Prior Informed Consent with Indigenous Peoples, Regarding Genetic Resources” by Roger Chennells
4.4.5 CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY Fifth meeting Nairobi, 15-26 May 2000 UNEP/CBD/COP/5/1. REPORT OF THE PANEL OF EXPERTS ON ACCESS AND BENEFIT-SHARING
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5. Bioprospecting/Access and Benefit-Sharing Case Studies
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5.1.5 Pharmaceutical Companies Partnered with International Cooperative Biodiversity Groups (ICBGs)
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5.3 SUMMARY/POINTS TO CONSIDER:
6. Types of Access and Benefit Sharing Agreements
6.1 Background
6.2 Types of Agreements.
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6.2.2 Sample Governmental Permits/Requirements.
6.2.3 Articles concerning the structure/types of Bioprospecting Agreements.
7. Important Contractual Terms to Consider
7.1 Role and responsibilities
7.1.1 Guidelines for Equitable Partnerships in New Natural Products Development Recommendations for a Code of Practice (Conclusions of the Workshop on Drug Development, Biological Diversity and Economic Growth, National Cancer Institute of the US National Institutes of Health, Bethesda, Maryland, 1991)
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7.1.2 The Conservation Finance Guide on Bioprospecting – a joint project of the Conservation Finance Alliance

7.2 Common Features
7.2.1 IUPAC - “General features of contracts for natural product collaborations”
7.2.2 IUPAC – “General features of contracts for natural product collaborations”
7.2.3 WIPO - Traditional Knowledge and Cultural Expressions – Contracts Database
7.2.4 Global Biodiversity Institute/International Institute for Tropical Agriculture Biodiversity, Biotechnology, and Law Training Course for West Africa
Module II: The Fundamentals for Bioprospecting Negotiations
7.3 Access to materials (genetic/biological)
7.3.1 Andean Pact: Common System on Access to Genetic Resources
7.3.2 Micro-Organisms Sustainable Use and Access Regulation: International Code of Conduct (MOSAICC)
7.3.3 Commonwealth Public Inquiry into Access to Biological Resources in Commonwealth Areas
7.3.4 The Model Law Of The Organisation Of African Unity On Community Rights And On The Control Of Access To Biological Resources (Third World Network)
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Seventh Asian Symposium on Medicinal Plants, Spices and Other Natural Products (ASOMPS VII)
7.4.5 People and Plants Online – Collecting Programmes
Exclusive and Non-Exclusive relationships
7.5 Types of benefits: ABS agreements can provide for a range of benefits, including financial (fees, royalties), conservation, and capacity building.
7.5.1 International Conservation Union (IUCN)
Sharing the Benefits from Genetic Resource Use (Biodiversity Brief 3)
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7.5.2 Implementing IPR and Benefit-Sharing Arrangements: Experiences in the University of Illinois at Chicago–Vietnam-Laos ICBG
7.5.3 Equitable Sharing of Biodiversity Benefits: Agreements on Genetic Resources
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1. Business of Bio-prospecting

While it can be argued that bioprospecting activities have always been part and parcel with large-scale corporate enterprises – either in the way of new sources for materials, new product development, or new markets. However, bioprospecting has gained more attention in recent years because of the growing awareness that new drugs will be urgently needed in the near future, either to cure currently incurable diseases that affect increasing numbers of the world population (AIDS, Alzheimers, TB, cancer) or else to replace drugs that are becoming increasingly ineffective to treat health problems (such as pathogens resistant to antibiotics). Bioprospecting activites are not limited to the pharmaceutical field alone – bioprospecting can impact any industry that relies (in whole or in part) upon the access, sourcing, processing or production of genetic resources to develop a commercially viable product for the world market. Bioprospecting activities also underpin the agricultural and food security sector (agribusiness and agrochemical industries), the cosmetics, health and beauty aids industries, and the biosafety sector. Bioprospecting is also inextricably linked to sustainable economic development, biodiversity conservation and equitable use and stewardship of global natural resources.

The outline below explores some of the resources on-line that cover these concerns.

1.1 Role of natural products in bioprospecting:

Biodiversity, Biotechnology and Law Training Course for West Africa

Module I – The Business of Biodiversity

http://www.aaas.org/international/africa/gbdi/

This module provides a brief overview of the global market for natural products and biodiversity-based drug discovery. Describes the drug discovery process, ethical and legal issues involved in current bio-discovery arrangements, and lists leading companies

in the agribusiness and pharmaceutical industries that dominate the market. Module concludes by listing priorities and agenda for West African countries in response to this expanding global market in biological resources and increased bio-discovery in developing countries.

1.1.1 Pharmaceutical Industry

Pharmscapec DeMontfort University

Leicester School of Pharmacy, U.K.

http://www.appsci.dmu.ac.uk/pharmscape/tour_1.htm

This web page provides an easily accessible and readable account of the drug discovery process, from initial discovery to development into a clinical drug. The web page discusses several issues along the

pharmaceutical pipeline, such as toxicology, strategies for locating potential sources of new drugs, and the chances that a prospective drug 12
actually makes it through all stages to a clinically-approved, saleable product.

Bioprospecting: MedicineQuest (An interview with Mark Plotkin)
http://www.actionbioscience.org/biodiversity/plotkin.html
This interview with ethnobotanist and author Mark Plotkin succinctly explores the reasons why protecting biodiversity is crucial to the discovery of new medicines and cures. Additional weblinks are also provided at the bottom of the page to related topics such as biopiracy, indigenous peoples rights, and biodiversity rights legislation.

"Rediscovering Natural Products", *Chemical and Engineering News* 81(41) (October 13, 2003), pp. 77-91. On-line at:
http://pubs.acs.org/cen/coverstory/8141/8141pharmaceuticals.html
This article discusses the demise of combinatorial chemistry's promise to discover new drugs faster than traditional natural products research for drug discovery, and how the pharmaceutical industry may once again look to natural products research for new leads because of advances in bioassay, screening, and structural elucidation technologies. The article also presents the debate over the intrinsic utility of many compounds in natural products over de novo compounds developed in the laboratory through combinatorial chemistry.

1.1.3 Agrochemical Industry

International Rice Research Institute – Rice Knowledge Bank – Agrochemicals in Perspective
http://www.knowledgebank.irri.org
Although the main focus of this website is on the improvement of rice cultivation worldwide, it provides a good overview of the issues in using agrochemicals for farming, and the rising demand for agrochemicals that are safe, environmentally friendly while also improving rice yields and improving the lives of rice farmers, most of whom are in poor and developing countries. Review of the business of agrochemicals.

1.1.3 Other (food security, GMOs, etc.)

Food Security News (Non-Wood News No. 7 (March 2000))
http://www.fao.org/docrep/x4945e/x4945e02.htm#P242_40958

A publication of the Wood and Non-Wood Products Utilization Branch of the FAO Forest Products Division, this issue examines the relationship between the commercialization of non-timber forest products and biodiversity, the eradication of poverty, sustainable development and food security. Near the bottom of this issue are a series of web links that
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discuss in-depth the issues relating to bioprospecting in Non-Timber Forest Products (NTFPs). Each issue also reviews the market outlook for new NTFPs.

1.2 Role of Traditional Knowledge

Science and Development Network (SciDevNet) Dossier:
Indigenous Knowledge (Introduction)
http://www.scidev.net/dossiers/index.cfm?fuseaction=dossierfulltext&Dossier=7

This website provides a brief overview on the value of indigenous knowledge systems and its contribution to sustainable development and the alleviation of poverty. Not only can indigenous knowledge provide a potential solution to local problems – such as time-honored remedies for local diseases, such as malaria – indigenous knowledge can be better implemented to solve local problems than frameworks or schemes that are foreign to the local context and insensitive to the peoples' lives and livelihoods in developing countries.

1.3 Market conditions relating to bioprospecting and TK –

(i) ten Kate, K and Laird, S.A., *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing* (Earthscan 1999).

This book remains a classic survey of the various commercial and research activities based on biodiversity prospecting.

1.4 Bioprospecting and Biopiracy

1.4.1 Bioprospecting: Legitimate Research or Biopiracy? By Graham Dutfield
http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&dossier=7&policy=40

This web page defines bioprospecting and biopiracy, while also presenting several sides of the debate: while some believe that ethical bioprospecting is possible, others believe it is an inherently flawed enterprise and that "fairness" to the communities who provide access to the commercially valuable biological resources can never be reasonably achieved. Dutfield also critically examines reported instances of patents placed on the traditional knowledge, and the effectiveness of international legislation to protect indigenous communities and

traditional knowledge.

1.4.2 Traditional Ecological Knowledge and Prior Art

http://www.wipo.org/patent/agenda/en/meetings/2002/presentations/hansen.pdf

This presentation provides an overview on the precarious position of traditional ecological knowledge in the Western intellectual property system – as something in the public domain to be exploited for individual gain, but which cannot be

recognized and protected as communally-held ecological knowledge. Approaches to how traditional ecological knowledge can be treated as "prior art", and therefore not exploitable by outsiders without compensation to the holders of this knowledge, are presented.

1.4.3 The International Debate on Traditional Knowledge as Prior Art in the Patent System: Issues and Options for Developing Countries (by Manuel Ruiz)

http://www.southcentre.org/publications/occasional/paper09/paper9-02.htm

This paper, available through the South Centre, outlines several ways in which treating traditional knowledge as prior art can be used to defensively protect traditional knowledge from being misappropriated by outsiders. Issues and options to consider when developing legal mechanisms for protecting traditional knowledge as prior art are also treated in-depth in Ruiz's report. A very helpful annex is also included.

1.4.4 Traditional Ecological Knowledge Prior Art Database (TEK*PAD)

http://ip.aaas.org/tekindex.nsf

This database is a searchable archive of traditional ecological knowledge documented worldwide. The purpose of this database is to use documentation and publication of traditional knowledge (in this case ecological knowledge practices) as a way to establish it as prior art, safeguarding it from misappropriation and patenting by outsiders. This site also contains additional resources, such as the Biopiracy Hotlist and the downloadable AAAS Handbook on Intellectual Property and Traditional Knowledge

1.4.5 Genetic Resources, Traditional Knowledge and Intellectual Property Rights Brief

www.ciel.org/Publications/iprights.pdf

A brief written on behalf of the World Summit on Sustainable Development in 2002, this report by the Center for International Environmental Law (CIEL) discusses ways in which the provisions of the CBD may be implemented nationally to promote and protect access to genetic resources and benefit-sharing

as well as safeguard indigenous peoples rights to their own communally-held knowledge, and the concomitant intellectual property component therein. A very concise treatment of the relationship between the CBD and TRIPS is provided, and also addresses the importance of the participation of indigenous and local communities in the debate over how indigenous intellectual property is to be defined and protected under the laws of member countries of CBD.

1.4.6 Science and Development Network (SciDevNet) Indigenous Knowledge Dossier

http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&policy=49&section=243&dossier=7

This thorough on-line resource covers both positive and defensive protection mechanisms for protecting indigenous knowledge in the public domain. The

commentary fairly and realistically assesses the utility and limitations of policy and laws to protect indigenous knowledge, and also discusses both sides of the debate to use databases to document traditional and indigenous knowledge and practices. The entire site has several links to other sources on the subject.

1.5 SUMMARY/POINTS TO CONSIDER

・Bioprospecting is big business. The potential for commercial gain is large, but so are the investment costs, with a high risk that no returns will appear.

・There are several kinds of bioprospecting; it covers everything from genomics to natural products research and everything in between.

・There is considerable controversy over what bioprospecting is, when it occurs, and whether it is a morally positive, neutral, or negative enterprise. Some proponents of bioprospecting believe that it is always a positive enterprise because the commercial gain enriches society at large, and the notion that bioprospecting could ever be “unethical” is wrong-headed. Conversely, critics of bioprospecting believe that it is an inherently flawed enterprise, incapable of ever being ethically sound or morally neutral (let alone a morally positive enterprise). Many others take a middle view and believe that bioprospecting can be conducted within an ethical framework, but only if certain protocols are first established in order to safeguard the intellectual property rights of all the parties in collaboration, especially the indigenous groups whose traditional knowledge is providing the lead for a potential new drug, new agricultural practice, or new cultural expression.

・While the literature focusing on bioprospecting is voluminous and will only

increase over time, there are still no clear-cut answers for how intellectual property rights should be defined, assigned and respected across all research contexts. And perhaps there will never be one simple answer to how to proceed; what instead might evolve are parallel sets of guidelines and protocols corresponding to specific kinds of bioprospecting research, from which individual groups and companies can decide and tailor how they want to conduct collaborative research, with equitable benefit-sharing in the case of a commercially viable product.

2. Legal Framework

2.1 International

2.1.1 TRIPS (Trade Related Aspects of Intellectual Property Rights)

a. Overview

TRIPS was adopted after the 1986 -1994 Uruguay Round of trade negotiations agreement by the World Trade Organization (WTO). TRIPS is perhaps the most influential international agreement on intellectual property rights. It outlines several important trade related aspects of intellectual property. 16

The agreement protects patents, copyright, trademarks, geographical indications, industrial designs, trade secrets, and new plant varieties. Its goal is to have intellectual property protection that will contribute to technical innovation and the transfer of technology while enhancing social welfare. The agreement provides equal treatment for all trading partners in the WTO. TRIPS requires that signatory states implement with minimum standards of protection for intellectual property in national systems, as well as enforcement provisions and methods of intellectual property dispute settlement. The TRIPS enforcement measures ensure that property right holders can effectively enforce their rights. These measures can be adopted as domestic procedures for the enforcement of intellectual property rights. They include civil and administrative procedures, provisional measures, special circumstances related to border measures, and criminal procedures.

Membership to the WTO requires a country to ratify TRIPS in order to gain access to multiple international markets available through WTO. Over three quarters of WTO member are developing or least developed countries.

TRIPS homepage on WTO website.

http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm

Text of TRIPS agreement

http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm
b. TRIPS/Patents
Overview: Section 27.1 of the TRIPS agreement requires that patents are made available for all inventions including products, process, and all fields of technology. Patents under TRIPS survive for 20 years and must be disclosed by publication [Article 29]. The 20-year time limit begins from the filing date, but the enforcement of rights only begin from the date of the patent grant.
The agreement states three exceptions that countries may rely on to exclude otherwise patentable subject matter. These are: 1) inventions contrary to public order or morality [Article 27.2]. 2) Diagnostic, therapeutic and surgical methods for the treatment of humans or animals [Article 27.3(a)]. 3) Plants and animals, including the biological processes for the production of plants or animals other than non-biological microbiological processes (not including microorganisms). Furthermore, effective *sui generis* method of protection for plant varieties must be adopted if the member chooses not to adopt a patent protection model.
c. TRIPS controversies:
(i) Overview: Much controversy has developed between the fusion of trade and intellectual property. Many argue that patenting restricts the availability of important products including pharmaceuticals. Such arguments contend that high prices of pharmaceuticals associated with patent monopolies are a key barrier to achieving broader treatment access in public and private health sectors, especially in developing nations. Developing
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nations have demanded an equitable access to needed medicine in areas of health without the morass of policies and patent obstacles.
(ii) DOHA DECLARATION
Overview: On November 2001, the WTO adopted the DOHA DECLARATION on TRIPS in response to the criticism by developing nations that pharmaceutical patents were creating obstacles in gaining access to important medicines. The declaration stresses the importance to implement and interpret TRIPS in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines. It

emphasizes that TRIPS does not, and should not, prevent member governments from acting to protect public health. It affirms governments' right to use the agreement's flexibilities in order to avoid any reticence the governments may feel.
T e x t o f D o h a d e c l a r a t i o n :
http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm
(iii) Pharmaceuticals/ Pre Doha:
This article addresses the problems that developing countries are facing in providing proper health care to their population. Developing countries are demanding a declaration by the WTO on their position to drug access. For example, the position by the Zimbabwe minister is that TRIPS rules should not impede WTO members from adopting measures to protect public health. The minister seeks flexible policies to ensure access to affordable medicines without necessarily constituting a violation of intellectual property rights. The Zimbabwean delegation stressed that numerous nations, such as South Africa, have faced legal problems due to the lack of clear interpretations of the TRIPS accord. During the WTO debate, the United States and Switzerland, countries that are home to the world's leading pharmaceutical laboratories, rejected the idea that TRIPS rules are obstacles to obtaining medications at low cost.
http://www.aegis.com/news/ips/2001/IP010905.htm
l
This memo provides a model for governmental use of compulsory licenses (authorization to use patents without the permission of the patent owner). The compulsory license model is to be used as a tool to increase access to medicines in developing countries. The model has five important features: 1) the system must not be overly legalistic, expensive to administer, or easily manipulated by litigation. It is recommended that the parties rely upon an administrative process, 2) The government use

provisions should be strong. No developing country
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should have statutory public use provisions that are weaker than the US, German, Irish, or UK provisions, 3) The system of setting compensation should be relatively predictable and easy to administer, 4) Production for export should be permitted, 5) There should be a provision for authorization of the use of patents to address public health emergencies.
http://www.cptech.org/ip/health/cl/recommendedstatepractice.html
This web site provides a list of different patent law schemes in developed countries. The list includes on what grounds compulsory licenses are issued, who makes the licensing decision, what provisions must be met for governmental use of patents, how compensation is determined, and notable patent exceptions.
http://www.cptech.org/ip/health/cl/examples2.html
(iv) Pharmaceuticals/ Post Doha
This opinion to the DOHA agreement, acknowledges the merits of the DOHA decision that permits developing countries to override drug patents and make and/or import generic copies of pharmaceutical products to meet their public health needs. However, the opinion notes that the rules regarding the method of obtaining such drugs was left open. Since DOHA, there has been retrogression on the parts of the developed countries- in particular the United States, EU, Japan and Switzerland. These countries are trying to negotiate a solution that will allow the fewest medicines permissible to treat very limited number of illnesses. European Commission (EC) is pushing for a set of highly restrictive "safeguards" on exports, including requirements on the packaging of generic products and notification to patent owners and the WTO. These obligations and others are allegedly designed to control diversions, or leakage, of

generic products into developed country markets where they could supposedly undercut patented drugs. The paper proposes regimes, with particular attention to coherence with internationally and democratically agreed upon principles of human rights, gender equality and sustainable development.
http://64.233.167.104/search?q=cache:sljfehFltLoJ:www.genderandtrade.net/WTO/TRIPS_PH.pdf+patent+Trips+pharmaceutical+controversy&hl=en&ie=UTF-8
Professor Chander, at UC Davis School of Law, discusses how the lack of needed drugs in developing
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countries is caused by the high cost of such medicines. For example, the anti-AIDS drug cocktails that are sold in U.S. for $10,000 a year can be generated in Indian laboratories and sold for $300 a year. Professor Chander notes that the problem with TRIPS is that the compulsory licenses are limited to the supply of domestic markets and not for export. Unfortunately, many countries do not have the manufacturing capacity to create pharmaceuticals and must import from other countries. DOHA was an attempt to solve the compulsory license issue, noting the gravity of public health concerns. Countries agreed to solve this issue of compulsory licensing before the end of 2002, but as of March 2003 no such agreement has been manifested. On December 2002, the EU, Japan, and Switzerland were ready to agree to a compromise to the issue, but the United States stopped the compromise. The United States felt the compromise was beyond the DOHA agreement, arguing that the agreement only targeted HIV/AIDS, tuberculosis, malaria, and a handful of other specified epidemics. Professor Chander's position is that the DOHA DECLARATION was not limited to the diseases specified in the text.

http://writ.news.findlaw.com/commentary/20030306_chander.html
On May 27 2002 the Zimbabwe Minister of Justice made an emergency declaration suspending the country's obligations under the TRIPS agreement with respect to patents on antiretroviral (ARV) and other drugs used in the treatment of HIV/AIDS. This constitutes the first time a country has invoked the DOHA DECLARATION on TRIPS and Public Health. Web page provides several links that discusses the debate and issues surrounding the DOHA DECLARATION.
http://www.eldis.org/ipr/news/2002jun_13_zimbabwe.htm
Announcement by the Office of United States Trade Representative (USTR), implementing an interim plan permitting poor countries to override patents on drugs produced outside their countries in order to fight current and future health epidemics. Such provisions were especially made to combat HIV/AIDS, tuberculosis, malaria and other diseases that pose national health crises. This announcement was made after the failed negotiations with WTO to rule on a consensus dealing with developing countries' access to patented medicines.
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http://usinfo.state.gov/ei/Archive/2003/Dec/31-624484.html
Article discusses the divergence between the goals of the DOHA DECLARATION and the intellectual property provisions proposed by the United States Trade Representative (USTR) within the Free Trade Area of the Americas (FTAA). If the planned measures were accepted, it would require a higher standard of protecting and enforcing IPRs on medicine that is already required by the WTO. The result would pose a serious threat to access to affordable medicines and public health in Latin America and the Caribbean. For example, the US is

seeking 5-years of exclusive rights for test data. Granting 5-years of data exclusivity would have the affect of establishing a 5-year ban on compulsory licensing. Under the DOHA DECLARATION, WTO members have the freedom to determine the grounds upon which to grant compulsory licenses. However, the US wants to limit the compulsory licensing to government use for only three circumstances: non-commercial use, situations of national emergency or other situations of extreme urgency, and to remedy anticompetitive practices. On August 30, 2003 WTO reached a temporary agreement that permits countries to issue compulsory licenses to export generic versions that have no manufacturing capacity. Proposed FTAA text would prohibit compulsory licensing for export altogether. Hence, countries that cannot produce medicines themselves would be unable to obtain low cost drugs from a foreign manufacturer in a country where a patent is on file. http://www.healthgap.org/press_releases/03/111903_HGAP_BP_FTAA_miami.pdf

This paper discusses Canada's proposed Government Bill C-56. The bill would amend the current Canadian Patent Act to provide for the issuance of compulsory licenses that would allow generic pharmaceutical manufactures to make and export generic versions of patented pharmaceutical products to developing countries lacking their own manufacturing capacity. The bill does not authorize compulsory licensing of pharmaceuticals to only treat specific diseases, nor is it limited to exporting to countries facing an "emergency" or other circumstances of extreme urgency. Some areas of the bill that must be considered before being passed are: 1) Provisions permitting patentholders to block licenses for generic manufacturers, 2) Limited list of pharmaceutical products, 3) Denial of

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benefit to some developing countries that are not WTO members, 4) No provision for NGOs to procure generic medicines.
http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend/PatentActAmendment_Update.pdf
This article discusses the problem of the high cost of medicines, which impedes the access to vital drugs in both developed and under developed countries. The current system of extending marketing monopolies on medicines worldwide prevents the very competition that reduces prices and increases access to life-saving medicines. The 20-year patent monopoly is provided to those manufactures that complete the research and development. The article suggests that the current business model that uses a single payment method for both cost of research and development has affected the cost of drugs. Alternatively, it proposes a new trade framework and business models for an effective virtual R&D market. One such measure would be to develop worldwide policies that encourage and reward innovation, while allowing competitors to build on each others' ideas, and protecting consumers from unreasonable prices. Other alternatives methods would require countries to maintain a GDP-related contribution to research and development, while being free to choose how they finance it. New methods of research - such as non-profit collaboration or prizes for exceptional ideas - would allow innovation to be rewarded directly, removing the need for marketing monopolies, and allow competition. Drugs could then be sold close to the cost of manufacture.
http://plosbiology.org/archive/1545-7885/2/2/pdf/10.1371_journal.pbio.0020052-L.pdf
2.1.2 Convention on Biological Diversity (CBD):
a. Overview
CBD is an international treaty on the conservation and sustainable use of biological diversity. It was created in 1992 at the Earth Summit in Rio De Janeiro.

Over 150 governments signed the document and since then more than 175 countries have ratified the agreement. Its three major goals are: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources. It also covers the rapidly expanding field of biotechnology, addressing technology development and transfer, benefit-sharing and biosafety. The treaty recognizes national sovereignty over all genetic resources, and provides that access to valuable biological resources be carried out on "mutually agreed terms" and subject to the "prior informed consent" (PIC) of the country of origin. When a microorganism,
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plant, or animal is used for a commercial application, the country from which it came has the right to benefit. Such benefits can include cash, samples of what is collected, the participation or training of national researchers, the transfer of biotechnology equipment and know-how, and shares of any profits from the use of the resources.

The CBD also recognizes the close and traditional dependence of indigenous and local communities on biological resources and the need to ensure that these communities share in the benefits arising from the use of their traditional knowledge. Member governments have undertaken "to respect, preserve and maintain" such knowledge and practices, to promote their wider application with the approval and involvement of the communities concerned, and to encourage the equitable sharing of the benefits derived from their utilization.

Official website: http://www.biodiv.org/default.aspx

b. Bonn agreement: (Created in 2002, during CBD's sixth meeting)

The guidelines cover areas related to genetic resources, as well as fair and equitable sharing of the benefits arising from their utilization. The guidelines should assist parties in creating an overall access and benefit sharing strategy, and identifying the steps involved in the process of obtaining access to genetic resources and benefit sharing. Specifically, these voluntary guidelines are meant to establish legislative, administrative or policy measures, negotiating contractual agreements for access and benefit sharing. The content of the guidelines coincides and directly supports several interpretations and concerns raised by developing countries including India, Brazil, and the Africa Group in the TRIPS Council under the review of Article 27.3(b) of the TRIPS Agreement. According to the Bonn agreement, the guidelines of prior informed consent include the following elements: consent of the national authority (including provincial and

local authorities) and of indigenous and local communities; mechanisms for the involvement of relevant stake holders; reasonable timing and deadlines; specification of the type of uses; direct linkage with mutually agreed terms; detailed procedures for obtaining the consent; and a description of the general process for access.

1. Official website:

a) http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp

2. BONN text:

a) http://www.biodiv.org/decisions/default.aspx?m=cop-06&d=24

3. http://www.southcentre.org/info/southbulletin/bulletin48/bulletin48-03.htm

c. Countries implementing CBD:

Article that discusses InBIO (Instituto Nacional de Biodiversidad), an institution developed in Costa Rica to promote bioprospecting and conservation efforts of Costa Rica's resources by developing negotiations and contracts with industrialized enterprises. InBIO has been successful in creating several agreements with foreign bioprospecting organizations. InBIO has seven key aspects that are manifested in their agreements: 1) Direct payments in cash or knowledge exchanges, 2) Payment of a significant percentage of the initial budget of the project [10%] and the returns of the commercialization of the products [50%], 3) Cooperation

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clauses that stipulate the gradual transition of the investigation processes to the supplier country, in order to create new jobs and the achievement of industrial development, 4) Minimum exclusivity, 5) Agreement on the samples property and patents property, 6) The use of chemistry synthesis, semi-synthesis and domestication of the living sources, in order to avoid the continuous extraction of the biotic material, 7) Legal mechanisms that will provide protection to all parties. Several examples of benefit sharing agreements are cited in this paper.

http://r0.unctad.org/trade_env/docs/Benefit Sharing.pdf

The Department of Environment and Heritage of Australia discusses its approach to the CBD. The goal is to guarantee that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia. The Department of Environment and Heritage's key policy aims include: providing greater

certainty for industry and researchers; requires the introduction of terms and conditions of access to Australian resources that Australia would be prepared to meet if introduced by other countries; respects indigenous biodiversity knowledge and its holders; requires consultation with stakeholders and indigenous peoples; and is flexible while encouraging cooperation between jurisdictions. The policies establish a common basis for new or revised legislation in all of Australia, creating a legal framework to promote biotechnology industry, acknowledging that this act is consistent with BONN guidelines. Further it ensures that traditional biological knowledge in the scientific, commercial and public domains proceeds only with the cooperation and control of the traditional owners of that knowledge and that the use and collection of that knowledge results in social and economic benefits to the traditional owners.
http://www.deh.gov.au/biodiversity/science/access/nca/pubs/understanding.pdf

This briefly summarizes the role of the CBD, as well as other national, regional, international and non-state initiatives in creating access to genetic resources and benefit-sharing systems. The different regimes offer insights into the relationship between international laws and access and benefit sharing (ABS). It proposes elements that should be included in an international system on ABS, as proposed at the World Summit on Sustainable Development in 2002. It suggests that such an international administration must have clear goals, be legally binding and should be broad in scope. Only in this fashion will countries be able to create a system that includes the environmental, social and economic aspects of sustainable development.
http://www.cisdl.org/pdf/brief_biodiv.pdf

Web site discusses World Wildlife Fund's (WWF) position on the access and benefit sharing as related to genetic resources. They support the efforts in promoting access to genetic resources and benefit sharing. However, WWF is concerned with the slow and unequal efforts to use the BONN guidelines to improve the natural resource management and
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guarantee benefits to indigenous and local communities. To address these concerns WWF calls on the conference of the parties of the CBD to increase and broaden capacity building exercises, improve information

sharing on lessons learned across nations and expand the dialogue and participation on the establishment of an international regime on access to genetic resources and benefit sharing.
http://www.panda.org/downloads/policy/cbd/wwfcop7absfinal3.do
c
2.1.3 Convention for the Protection of New Varieties of plants (UPOV)
a. Overview- UPOV was established in 1961 and it was revised in 1972, 1978 and 1991. Its objective is to provide and promote an effective system of plant variety protection with the aim of encouraging the development of new varieties of plants
for the benefit of society. The UPOV Convention provides a *sui generis* form of intellectual property protection, which has been specifically adapted for the process of plant breeding. The 1991 convention requires member countries provide protection to new plant varieties by way of Plant Breeder's Rights. Not all members are required to be
bound by the 1991 convention. Original members can decide to be bound by a previous agreement. Unlike the previous UPOV agreement, there is no farmer's or breeder's exemption for protected species. It is now up to the national governments to implement separate legislation with respect to this practice. Many UPOV members are also WTO members and therefore obliged to protect plant varieties by a *sui generis* protection system (as a result of the TRIPS Agreement that requires protection of plant variety either
through: (a) patents, (b) effective *sui generis* systems, or (c) any combinations thereof.) While the precise meaning of *sui generis* under TRIPS is unclear, the use of the UPOV plant protection system generally fulfills this requirement. As a result the use of UPOV for plant protection is a mechanism for complying with the TRIPS Agreement.
Official UPOV website: http://www.upov.int/
b. UPOV controversy- Because *sui generis* has not been clearly defined, there has been much controversy as to the interpretation of *sui generis* and what is considered an effective *sui generis* scheme. Many argue that *sui generis* permits countries to create their own protection for plant varieties. While others advocate that UPOV's plant breeders rights system is the best *sui generis* protection available. Many developing countries disfavor using the UPOV standard.
The South Asia Watch on Trade, Economics & Environment (SAWTEE) and the International Center for Integrated Mountain Development (ICIMOD), together with several other regional organizations, has developed a program to protect mountain

farming communities. SAWTEE states that most developing countries have chosen to implement their own *sui generis* systems. Most developing countries have chosen the *sui*
generis system. However, developed countries, through bilateral pressure tactics (including during the accession of new countries to the WTO), are trying to impose their own model, known as International Union for the Protection of New Plant Varieties (UPOV) on the developing countries. Developed countries have gone on record claiming UPOV as the only effective *sui generis* model, thus facilitating the process of its backdoor entry into the WTO system. These moves by the developed countries, made at the insistence of the multinational seed companies based in their respective countries, are
calculated to restrict the farmers' rights with the twin objectives of: a) making farmers 25
dependent on them for the purchase of seeds "at any price"; b) driving the farmers (who are their competitors by virtue of being able to supply nearly 80 percent seed requirement
in the developing countries) out of the market and establishing control over the entire market.

http://www.sawtee.org/Third_Regional_Consultation_Sri_Lanka.html

Web site that criticizes the globalization of IPR campaign and the interests of transnational corporations housed in the North. The web site alleges that UPOV is currently selling itself as the ready-made solution for compliance with TRIPS. Even though TRIPS makes no mention of UPOV, UPOV wants every developing country to believe that joining its ranks is the simplest and most logical means to comply with the former trade regime. However, countries do not have to join UPOV to implement a *sui generis* system as compliance with TRIPS. The web site provides ten reasons why not to join UPOV.

http://www.southcentre.org/southletter/sl34/sl34-10.htm

Memorandum discusses how much of the genetic biodiversity is found on the southern hemisphere in developing countries. Their food security often depends on traditional agriculture, cultural systems and the knowledge and ability to use different plants and plant varieties of indigenous peoples and farming communities. Developing countries often agree to join the UPOV for its preferential trade relations with the EU or
development assistance. However, small-scale farmers in these developing countries are negatively affected because they must now buy seeds patented by companies.

Traditionally, small-scale farmers have saved seeds for cultivation and exchanged and sold them locally. For example, in Sub-Saharan Africa 90 percent of food production is based on seeds saved for cultivation and in India the percentage is 70. In industrialized countries, too, farmers prefer to save seeds rather than buy new ones. UPOV guarantees
companies that trade in seeds extensive rights to protect seeds and a monopoly position in
the markets, which affect the overall food security and, community rights of indigenous people.
http://www.kepa.fi/english/cancun/trips_agreement/index_html?printable
2.1.4 United Nations Educational, Scientific and Cultural Organization (UNESCO)
a. Overview: UNESCO works as a laboratory of ideas and a standard-setter to forge universal agreements on emerging ethical issues. The organization also serves as
a clearinghouse that disseminates and shares information and knowledge, while helping
member states to build their human and institutional capacities in diverse fields. In short,
UNESCO promotes international co-operation among its 190 member states and six associate members in the fields of education, science, culture and communication.
Official Website:
http://portal.unesco.org/en/ev.php@URL_ID=3328&URL_DO=DO_TOPIC&URL_SECTION=201.html
b. Safeguarding Traditional Cultures: A Global Assessment of the 1989 UNESCO Recommendation on the Safeguarding of Traditional Culture and Folklore (Center for Folklife and Cultural Heritage, Smithsonian Institution, Washington, DC). This volume is from the conference entitled “A Global
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Assessment of the 1989 Recommendation on the Safeguarding of Traditional Culture and Folklore: Local Empowerment and International Cooperation” held at the Smithsonian Institution in Washington, D.C., from June 27–30, 1999. Though the United States is not a member of UNESCO and the Smithsonian not officially charged with representing official policy, long standing concern and involvement with the issues of traditional culture and folklore brought the two institutions together to organize the conference which addressed many aspects of Traditional

Knowledge and UNESCO's efforts in this area.
http://www.folklife.si.edu/unesco/
c. UNESCO TK, Farmers Rights and *Sui generis* protection
Final declaration by Pacific Island territories for protection of indigenous cultures and their intellectual property. Declaration stresses the need for a collective voice for the Pacific Islands in the international forum and for concrete and effective measures at national, regional and international levels in the region. Declaration consists of: 1) the definition of traditional knowledge and expressions of the indigenous cultures of the Pacific Islands, 2) the Pacific position on the international debate on the protection of traditional knowledge and expressions of indigenous cultures, 3) recommendations for a policy of regional harmonization of the protection of traditional knowledge and expressions of indigenous cultures, 4) recommendations for technical assistance and support of a homogenous system of legal protection, identification, conservation and control of exploitation, of indigenous culture in the countries and territories.
http://www.unesco.org/culture/copyright/folklore/html_eng/declaration.sht
ml
Additional UNESCO-WIPO declarations:
a) WIPO-UNESCO African Regional Consultation on the
Protection of Expressions of Folklore (Pretoria, South Africa)
http://www.wipo.int/documents/en/meetings/1999/folklore/
index.htm#africa
b) WIPO-UNESCO Regional Consultation on the Protection of
Expressions of Folklore for Arab Countries (Tunis, Tunisia)
http://www.wipo.int/documents/en/meetings/1999/folklore/
index.htm#arab
c) WIPO-UNESCO Regional Consultation on the Protection of
Expressions of Folklore for Latin America and the Caribbean
(Quito)
http://www.wipo.int/documents/en/meetings/1999/folklore/
index.htm
2.1.5 The World Intellectual Property Organization (WIPO)
a. Overview: an international organization dedicated to promoting the use and protection of works of intellectual property. Headquartered in Geneva, Switzerland, WIPO is one of the 16 specialized agencies of the United Nations system of organizations. It administers 23 international treaties dealing with different aspects of

intellectual property protection. The Organization counts 180 nations as member states.

In 1981, WIPO-UNESCO jointly adopted a Model Law on Folklore.

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Official website:

http://www.wipo.int/about-wipo/en/overview.html

Traditional knowledge and cultural expressions: WIPO web page, which provides links to issues, news, and resources, relating to traditional knowledge, genetic resources, and cultural expressions (folklore).

http://www.wipo.int/tk/en/index.html

b. WIPO TK, Farmers Rights and *Sui generis* protection

October 2003- WIPO announces that the WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), will be accelerating its work in the international dimension of intellectual property (IP) and genetic resources, traditional knowledge (TK) and folklore. IGC first met in April 2001 to discuss how intellectual property systems may protect TK, expressions of folklore, and how to handle issues of genetic resources. The IGC has fostered exchange of practical understanding of the approaches available for legal protection of traditional knowledge and cultural expressions. A detailed overview of the work of the IGC is provided in document WIPO/GRTKF/IC/5/12 (available in Adobe PDF and MS-Word formats).

http://www.wipo.int/pressroom/en/releases/2003/p362.htm

http://www.grain.org/bio-ipr/?id=364

March 2004- The ICG decided on concrete steps for accelerated international work on protection of traditional knowledge (TK) and folklore. This was the first meeting of the IGC since its mandate was renewed by the WIPO General Assembly in October 2003 with instructions to accelerate its work and focus on the international dimension of intellectual property (IP) and genetic resources, TK and folklore. During its meeting from March 15 to 19, the IGC commissioned the development of two complementary sets of core materials for TK and for folklore. In each case, the IGC approved the development of an overview of policy objectives and core principles for protection, and an outline of the policy options and legal mechanisms, backed up by precise analysis of the implications of each option. The African group of countries submitted a text on objectives, principles and elements of an international instrument. This proposal received widespread support in the Committee as a framework for its work. The

Committee also considered a range of practical steps to enhance the participation of representatives of TK holders, and launched a new website: http://www.wipo.int/tk/en/igc/ngo/index.html to disseminate position papers of IGC observers that would enhance awareness of the perspectives and concerns of TK holders.

http://www.wipo.int/edocs/prdocs/en/2004/wipo_pr_2004_378.html

WIPO introduces a group case study on the use of intellectual property systems by indigenous communities in Australia. The publication, entitled, 'Minding Culture: Case Studies on Intellectual Property and Traditional Cultural E x p r e s s i o n s ' http://www.wipo.int/tk/en/studies/cultural/mindingculture/studies/finalstudy.pdf, was written for WIPO by Ms. Terri Janke, an Australian lawyer and a descendant of the Meriam people of the Torres Strait Islands, Australia. The studies were created to assist WIPO in responding to

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intellectual property systems in the areas of traditional cultures and knowledge. The case studies provide traditional communities, as well as policymakers, legislators and other stakeholders, with realistic, empirically-based options and new ideas for future policy development.

http://www.wipo.int/edocs/prdocs/en/2004/wipo_pr_2004_377.html

Paper written by Dr. Patricia Kameri-Mbote covering topics on community, as well as farmers and breeder's rights in Africa. Kameri-Mbote notes that there is reluctance in many developing countries to implement TRIPS provision because the underlying IPR regimes that are based on western concepts of property rights are alien to the cultural, historical and institutional context of most developing countries. This paper analyzes the international and Kenyan legal framework for the protection of biodiversity and plant varieties. It seeks to identify cross cutting issues and trends pertinent to the protection and enforcement of community, farmers' and breeders rights through *sui generis* systems. It advocates that countries should seize the opportunity to implement *sui generis* systems provided through TRIPS to protect plant varieties. Kameri-Mbote provides example guidelines on formulating *sui generis* policies and legislation, which entails community rights, farmer's rights, breeder's rights, benefit sharing, and institutional and administrative frameworks. She dismisses the use of UPOV because of its patent rights that in turn create monopolies that favors countries with highly industrialized agricultural sectors.

http://www.ielrc.org/Content/A03021P.pdf

2.2 National

2.2.1 Background

In most instances, national governments are solely responsible for implementing intellectual property laws and granting individuals, groups and companies intellectual property rights to their creations in a manner consistent with international obligations. While they differ from country to country, copyright, trademark, patent, and other intellectual property laws have largely been harmonized throughout the world due to various international treaties and conventions. Despite this movement toward standardization of national laws, differences in terms of protection and additional IPR developments do exist. This section contains various links to sites highlighting national intellectual property legislation and recent developments of relevance to access and benefit sharing arrangements.

2.2.2 Intellectual Property Rights Variations

a. WIPO Guide to Intellectual Property Law Worldwide

http://www.wipo.int/about-ip/en/ipworldwide/index.html

This site identifies the intellectual property legislation in 219 nations, along with their adherence to bilateral and multilateral treaties. Individual profiles are given for each country that provides information on country specific legislation and activities, administrative structures,

and on governmental and non-governmental bodies for information and enforcement. Full-text reproductions of national legislation are not given.

b. Caslon Intellectual Property Guide:

http://www.caslon.com.au/ipguide5.htm

This page highlights intellectual property developments in particular countries and regions. Summaries for recent national developments in intellectual property law are given for the following: the USA, European Union, UK, Canada, New Zealand, China, and Japan.

c. WIPO: Collection of Laws for Electronic Access

http://clea.wipo.int/clea/lpext.dll?f=templates&fn=mainh.htm&2.0

Collection of Laws for Electronic Access (CLEA) database is an international electronic archive of national intellectual property legislation. It provides full-text reproductions of national legislation in

English. The CLEA database also includes the texts of selected laws in French and Spanish. The CLEA database also bibliographic references to many more pieces of legislation not translated.

d. Collection of national copyright laws

http://portal.unesco.org/culture/en/ev.php@URL_ID=14076&URL_DO=DO_TOPIC&URL_SECTION=201.html

e. Researching Intellectual Property Law in an International Context

http://www.llrx.com/features/iplaw2.htm

This site contains various links to international intellectual property regimes as well as links to a large number of national intellectual property laws.

f. Examples of national legislation:

a) Andean Community (2002): Decision 486 on a Common Regime on Industrial Property

b) Organization of African Unity (OAU) (1999): Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders and Regulation of Access to Biological Resources

c) Peru (2002): Law 27811 on the Protection of Collective Knowledge of Indigenous Peoples Related to Biological Resources

d) Philippines (1996): Executive Order 247 on Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By Products and Derivatives, for Scientific and Commercial Purposes and Other Purposes

2.3 Rights and Interest of Indigenous People

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While historical trends in international law previously facilitated the colonization of indigenous peoples and their lands, modern international law's human rights programs have gradually become more responsive to indigenous peoples' desires to survive as distinct communities in control of their own lives. This has become particularly more evident in the international system over the last several years. The United Nations and other international institutions have come to exhibit a renewed focus on many concerns and interest of indigenous peoples. The most prominent of these concerns that has been addressed is indigenous peoples' right of self-determination. Self determination has been generally defined as the right for all peoples to determine their own economic, social and cultural development.

In exercising this right of self-determination, indigenous peoples argue for recognition that they are also to be in control of their cultural and intellectual property. This section contains various links addressing these topics.

2.3.1 Position of Indigenous people within state legal framework

a. Self-determination and international law

(i) The Principle of Self-Determination and Indigenous Peoples Under International Law, James Anaya

http://www.austlii.edu.au/au/other/IndigLRes/car/1997/3/speeches/plenary2/anaya.htm

This paper is based on a chapter in James Anaya's book, *Indigenous People in International Law*. The paper's main focus is to address the meaning of self determination. Anaya establishes the core ideas behind the principle in order to give a greater view to the scope and content of self-determination as a principle of international law. Anaya also discusses the general reasons that resistance has arisen in acknowledging the principle. Anaya discusses that the foundation of most of the resistance is the misconception that self-determination equates to indigenous peoples having a right to choose independent statehood or some other form of political arrangement.

(ii) Indigenous Affairs: Self Determination

http://iwgia.inforce.dk/graphics/Synkron-Library/Documents/IndigenousAffairs/selfdetermination.pdf

This issue contains an article by John Henriksen addressing the scope of self-determination and the intended beneficiaries of this principle. The issue also contains several articles highlighting specific indigenous peoples' struggles for self-determination.

(iii) General link to other Self Determination writings

http://www.iwgia.org/sw228.asp

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b. Some examples of self-determination and international law:

The right of self-determination has been recognized in many international instruments. It is embodied in the Charter of the United Nations, the International Covenant on Civil and Political Rights, and the International Covenant on Economic, Social and Cultural Rights. The common article of these covenants provides that:

1. All peoples have the right of self-determination. By virtue

of that right they freely determine their political status and freely pursue their economic, social and cultural development.
2. All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic co-operation, based upon the principle of mutual benefits, and international law. In no case may a people be deprived of its own means of subsistence.
3. The States Parties to the present Covenant, including those having responsibility for the administration of Non-Self-Governing and Trust Territories, shall promote the realization of the right of self-determination, and shall respect that right, in conformity with the provisions of the United Nations.
(i) International Covenant on Civil and Political Rights
http://www1.umn.edu/humanrts/instree/b3ccpr.htm
(ii) International Covenant on Economic, Social and Cultural Rights
http://www.unhchr.ch/html/menu3/b/a_cescr.htm
(iii) Charter of the United Nation
http://www.un.org/aboutun/charter/
2.3.2 Some declarations from indigenous groups:
Despite international recognition of the rights of indigenous peoples, the knowledge and way of life of indigenous people are still perceived to be threatened. As a result of this, various initiatives and declarations have been launched to protect the rights of indigenous peoples. Many of these declarations focus on the perceived limitations of existing intellectual property laws and the future development of sui generis legislative frameworks to protect indigenous cultural and intellectual property rights. These declarations or soft laws, though not legally binding, are regularly used to exert moral and political influence in order provide direction for the creation of these beneficial sui generis systems.
a. Mataatua Declaration
http://users.ox.ac.uk/~wgtrr/mataatua.htm
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The Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples was drawn up in June 1993 in New Zealand. In the declaration, indigenous delegates from fourteen countries stated their right to self-determination and proclaimed indigenous peoples as the

exclusive owners of their cultural and intellectual property. The declaration further offers recommendations to indigenous peoples in developing policies and practices reflective of this. The declaration's policy recommendations call for such things as: (1) indigenous people defining for themselves their own intellectual and cultural property, (2) a recognition that existing protection mechanisms are insufficient for the protection of indigenous people's intellectual and cultural property rights, and (3) establishing appropriate mechanisms for monitoring the commercialism if indigenous cultural property in the public domain. The declaration also offers detailed recommendation to states and international agencies in developing appropriate policies that recognize indigenous peoples as the guardians of their customary knowledge, who have the right to protect and control dissemination of their knowledge.

b. Other Declarations

(i) Kari-Oca Declaration

http://www.tebtebba.org/tebtebba_files/susdev/susdev/karioca.html

The Kari Oca Declaration was written at the World Conference of Indigenous Peoples on Territory, Environment and Development held in Rio de Janeiro in May of 1992. At the Conference, indigenous representatives from all over the world met together to write the document asserting their basic and fundamental rights. The Kari-Oca Declaration broadly asserts indigenous peoples' rights to their land and traditions, and their commitment to protect the resources under their control for future generations. In addition to this, the declaration establishes a framework outlining the relationship between indigenous peoples and the international community

(ii) Indigenous Peoples Earth Charter

http://www.tebtebba.org/tebtebba_files/susdev/susdev/earthcharter.html

The 109-point Earth Charter elaborates on the principles of the Kari-Oca Declaration. It denounces specific practices which threaten indigenous societies and cultures, such as population transfer schemes and toxic and nuclear waste dumping on indigenous lands. It also demands that indigenous treaties be taken seriously by governments and calls for UN enforcement of them. It also proposes that the United Nations, at the request of affected indigenous peoples, be given the authority to send indigenous representatives, in a peacekeeping capacity, into territories

where conflicts arise. The Charter demands that governments demarcate indigenous lands and grant indigenous people autonomy over them. It emphasizes the importance of indigenous people cultivating local crops
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for local consumption and it holds that indigenous peoples have a right to maintain their traditional way of life.

(iii) Declaration of Belem

http://users.ox.ac.uk/~wgtrr/belem.htm

The Declaration of Belem is a product of the First International Congress of Ethnobiology (1988), which was convened by indigenous peoples, scientist, and environmentalists in order to discuss and formulate a policy to prevent the destruction of cultural and biological diversity. Within the Declaration, an acknowledgment is given to the pivotal role that indigenous peoples play in maintaining biodiversity. The Declaration further outlines the responsibilities of scientists and environmentalists in addressing the needs of these local communities. Notably, the Declaration calls for mechanisms to be created that recognize indigenous specialists as proper authorities to be consulted in all programs affecting them, their resources, and their environments. The Declaration also calls for procedures to be developed to compensate native peoples for their knowledge and for the use of their biological resources.

(iv) Suva Declaration

http://users.ox.ac.uk/~wgtrr/suva.htm

In supporting the initiatives of the Mataatua Declaration and the Kari-Oca Declaration, the Suva Declaration recognizes the rights of indigenous peoples of the Pacific to self-governance and independence and ownership of lands, territories and resources. In the statement these rights are seen as the basis for the preservation of indigenous peoples' knowledge and culture. The statement also calls for a recognition of the limitations of current intellectual property laws and the need for protective measures to ensure against possible exploitation.

(v) The Manila Declaration

http://users.ox.ac.uk/~wgtrr/asomps.htm

(vi) General link to statements, declarations, charters, resolutions and recommendations by organizations representing indigenous and local

communities
http://www.biodiv.org/programmes/socio-eco/traditional/instruments.asp
http://users.ox.ac.uk/~wgtrr/decin.htm
2.3.3 Examples of State Legislation Relating to Indigenous Knowledge
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a. Indigenous Peoples' Rights Act
http://www.grain.org/docs/philippines-ipra-1999-en.pdf
The Indigenous Peoples' Rights Act was signed into Philippines law in 1997. The law seeks to recognize, protect, and promote the rights of indigenous peoples in the Philippines through a variety of implementing mechanisms. The act specifically defines a range of rights of indigenous peoples, but with much focus towards giving proper recognition to the indigenous peoples' rights to self-governance and to their ancestral domains.
b. Peru: Legislation implementing protection regime for the collective knowledge if indigenous peoples derived from biological sources.
http://www.grain.org/brl/peru-tk-2002-en.cfm
This legislation by the Peruvian government establishes a special protection regime for the collective knowledge of indigenous peoples that is connected with biological resources. The regime's objective are to (a) To promote respect for and the protection, preservation, wider application and development of the collective knowledge of indigenous peoples; (b) To promote the fair and equitable distribution of the benefits derived from the use of that collective knowledge; (c) To promote the use of the knowledge for the benefit of the indigenous peoples and mankind in general; (d) To ensure that the use of the knowledge takes place with the prior informed consent of the indigenous peoples;(e) To promote the strengthening and development of the potential of the indigenous peoples and of the machinery traditionally used by them to share and distribute collectively generated benefits under the terms of this regime; (f) To avoid situations where patents are granted for inventions made or developed on the basis of collective knowledge of the indigenous peoples of Peru without any account being taken of that knowledge as prior art in the examination of the novelty and inventiveness of the said inventions.

c. Panama:
http://www.grain.org/brl/panama-tk-2000-en.cfm
The purpose of this law is to protect the collective rights of intellectual property and traditional knowledge of the indigenous communities upon their creations such as inventions, models, drawings and designs, innovations contained in the pictures, figures, symbols, illustrations, old carved stones and others; likewise, the cultural elements of their history, music, art and traditional artistic expressions, capable of commercial use, through a special registration system, promotion, commercialization
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of their rights in order to stand out the value of the indigenous cultures and to apply social justice.
2.3.4 Protocols to meet with outsiders
a. Hopi:
http://www.nau.edu/hcpo/hcpo/index.html
Due to perceived abuses, misrepresentation and exploitation of the rights of the Hopi people, community guidelines were established in order to protect their intellectual and cultural resources. This protocol for research, publication and recordings, requires that the Hopi Tribe be consulted for all projects or activity involving Hopi intellectual resources and that such projects or activity be reviewed and approved by the Hopi Office of Historic and Cultural Preservation. This is to be accomplished through a permitting process or other contractual agreement. Proposals for permission shall address, at a minimum, the following: (1) Intent and benefit to the Hopi tribe, (2) Risks associated with the activity, (3) Detailed mechanism for informed consent, (3) Mechanisms for protecting the right to privacy of the Hopi people, (4) Fair and appropriate return, (5) Review of the research, (6) Ownership.
b. Alaska Native Knowledge Network:
http://www.ankn.uaf.edu/standards/knowledge.html
This contains suggested guidelines for indigenous peoples to address issues of concern in the documentation, representation and utilization of traditional cultural knowledge by such individuals as researchers, authors and publishers. These guidelines are party specific but generally call for measures to ensure interested parties take necessary steps in obtaining informed consents, and that appropriate efforts are undertaken

in order to ensure that any representation of cultural content is accurate, contextually appropriate, explicitly acknowledged and approved by proper authorities.

3. Ethical Codes and Institutional Policies and Guidelines for Bioprospecting. Ethical codes, which may be mandatory or aspirational, generally set forth underlying principles for research, whereas guidelines and policies often supplement ethical codes and tend to provide more practical advice as to "best practices." This section contains links to numerous ethical codes, policies and guidelines put forward by (i) research institutions, (ii) state governments, intergovernmental and non-governmental organizations, and (iii) private corporations. Codes and Guidelines can be very useful in bioprospecting arrangements even where members of organizations to which the codes and guidelines apply are not involved, as they can provide some indication of relevant "best practices."

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3.1 Professional Societies and Research Institutions Ethical Codes and Guidelines

3.1.1 1996 Proposed Guidelines for Researchers and Local Communities Interested in Accessing, Exploring and Studying Biodiversity; developed by the Biodiversity & Ethics Working Group of Pew Conservation Fellows. http://wwwgeography.

berkeley.edu:16080/ProjectsResources/BRP/BRP.pdf

This Directory of Guidance Documents Relating to Biodiversity and Cultural Knowledge Research and Prospecting was compiled for the Biodiversity & Ethics Working Group of Pew Conservation Fellows By Tegan Churcher, Research Asst. for Dr. Ashok Gadil & Dr. Bernard Nietschmann; Department of Geography, University of California and Environmental Energy Technologies Division Ernest Orlando of Lawrence Berkeley National Laboratory Berkeley, CA in June 1997. This document describes in detail biodiversity research protocols proposed by the Pew Conservation Fellows, and provides a survey of biological and cultural research and prospecting protocols, along with a bibliography. The principles underlying the Pew guidelines are as follows: (1) Research should be an educational process leading to mutual learning among researchers and the collaborating individuals, communities and institutions; (2) Just as the propriety rights of scientific knowledge are

well established and respected, such rights are due to the producers and providers of traditional knowledge and contemporary innovations from local communities; (3) Research should be based on respect for the local cultural values and norms; (4) Benefits should accrue to all partners in a fair and equitable manner; and (5) Informed consent should be obtained within limits of practicality.

3.1.2 Botanic Gardens

a. Royal Botanic Gardens, Kew: Principles on Access to Genetic Resources and Benefit-sharing for Participating Institutions

(i) Principles:

http://www.rbgkew.org.uk/conservation/principles.html

In furtherance of the CBD, The Convention on International Trade in Endangered Species of Wild Fauna and Flora, the Principles sets forth key elements relating to the acquisition, use, and supply of genetic resources; advocates the use of written agreements where required by law and in accordance with “best practices”; calls for the fair sharing of benefits not only with the source country, but also other stakeholders; addresses record maintenance; and calls on participating institutions to develop and implement policies to effectuate the Principles.

(ii) Participants:

http://www.rbgkew.org.uk/conservation/endorsements.html

b. Missouri Botanical Garden, Natural Products Research Policy http://www.mobot.org/MOBOT/Research/applied_research/policy.shtml

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Contains specific guidelines and requirements relating to contracting and benefit sharing, including that an appropriate percentage of the profits generated by any products developed will return to the source-country, that the source-country will have "first right of refusal" to develop an appropriate and sustainable supply of raw biological source materials necessary for the continued research development and/or eventual commercial production of any product, and that opportunities for research originating as a direct result of any program are shared in an equitable manner between the Missouri

Botanical
Garden (MBG) and collaborating source-country institutions. In addition, the Policy recognizes that the success of a research program aimed at the commercial development of a natural product depends upon the substantial intellectual contribution of all of the participants, and sets forth some guidelines on intellectual property treatment, including
(i) patents for all inventions arising from collaborative research will be the responsibility
of commercial partners, (ii) the MBG will only enter into commercial research agreements with a provision insuring that royalties will be paid to source-country in the event a discovery is marketed and generates profits, and (iii) in the event that a discovery
is commercialized, MBG will use reasonable efforts to ensure that all royalties will be paid to an appropriate source-country organization, and the MBG will not receive any percentage of such royalties.

3.1.3 International Society of Ethnobiology (ISE), Code of Ethics
http://guallart.dac.uga.edu/ISE/SocEth.html
The purpose of this Code of Ethics is: to optimize the outcomes and reduce as much as possible the adverse effects of research (in all its forms, including applied research and development work) and related activities of ethnobiologists that can disrupt
or disenfranchise indigenous peoples, traditional societies and local communities from their customary and chosen lifestyles; and to provide a set of principles to govern the conduct of ethnobiologists and all members of the International Society of Ethnobiology (ISE) engaged in or proposing to be engaged in research in all its forms, especially collation and use of traditional knowledge or collections of flora, fauna, or any other element found on community lands or territories.

3.1.4 Society for Economic Botany, Professional Ethics in Economic Botany: A Preliminary Draft of Guidelines
http://users.ox.ac.uk/~wgtrr/seb.htm
Addresses ethical issues faced by economic botanists, related both to their data collection needs and methods, and to the dissemination and use of their findings. This document presents guidelines for professional behavior for members of the Society for Economic Botany and outlines responsibilities to the public, those studied, host governments and institutions, the profession, and sponsors. For example, it requires members to communicate clearly and honestly to all informants, the objectives and

possible consequences of ones' research. Several provisions apply to bioprospecting: If the research has a commercial objective, the member must make that explicit and disclose
what the commercial results might reasonably be expected to be. In addition, the member
will respect any request for confidence made by those providing data or materials, provided that the maintenance of such confidence does not compromise other ethical considerations. When materials or information obtained from informants can reasonably
be expected to have commercial payoff, the member should arrange with employers for 38
equitable economic compensation for the individual(s) and will do all in their power to ensure that compensation is paid.

3.1.5 American Anthropological Association, Code of Ethics
http://www.aaanet.org/committees/ethics/ethcode.htm

The Code of Ethics addresses in some detail issues around informed consent, among other topics. It provides that anthropological researchers should obtain in advance
the informed consent of persons being studied, providing information, owning or controlling access to material being studied, or otherwise identified as having interests which might be impacted by the research. It is understood that the degree and breadth of
informed consent required will depend on the nature of the project and may be affected by requirements of other codes, laws, and ethics of the country or community in which the research is pursued. Further, it is understood that the informed consent process is dynamic and continuous; the process should be initiated in the project design and continue through implementation by way of dialogue and negotiation with those studied.

Researchers are responsible for identifying and complying with the various informed consent codes, laws and regulations affecting their projects. Informed consent, for the purposes of this code, does not necessarily imply or require a particular written or signed
form. It is the quality of the consent, not the format, that is relevant.

3.1.6 American Folklore Society, Statement of the American Folklore Society On Research with Human Subjects
http://www.afsnet.org/aboutAFS/humansubjects.cfm

In addition to an admonition against exploiting individual informants for personal gain, the AFS States calls for a fair return to informants for all services. There is also an obligation to reflect on the foreseeable repercussions of research and publication on the general population being studied. As part of obtaining informed consent, the anticipated consequences of the research should be communicated as fully as possible to the individuals and groups likely to be affected. Unlike several other professional codes of ethics which mandate or at least privilege written agreements, the AFS Statement posits
that written agreements are inconsistent with building trust: “The nature of the relationships that folklorists build with their consultants, however, is such that a written,
signed, legally effective document would be inimical to the relationship upon which folklore research is based. Folklorists cannot go as guests into people's home communities, build trust and friendships, and then present a legal document for signature.
Nor can they ask for signatures to be witnessed. Informed consent is given orally, and possibly can be recorded on audio- or videotape, but introducing a written legal document
into the folklorist-consultant relationship would generally prove an insult to the consultant and bring folklore research to a halt. Institutional review boards should alter or
waive the requirements for written informed consent in the case of folklore and other forms of ethnographically based research.”
3.2 International Governmental Organizations
3.2.1 Bonn Guidelines
http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp
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http://www.biodiv.org/decisions/default.aspx?m=cop-06&d=24&print=1
The Bonn guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization were recognized as a useful first step of an evolutionary process in the implementation of relevant provisions of the Convention related to access to genetic resources and benefit-sharing. These voluntary guidelines are meant to assist Parties, Governments and other stakeholders when establishing legislative, administrative or

policy measures on access and benefit-sharing and/or when
negotiating contractual arrangements for access and benefitsharing.
3.2.2 The International Code of Conduct for Plant Germplasm Collecting and Transfer
http://www.fao.org/ag/agp/agps/pgr/icc/icce.htm
The International Code of Conduct for Plant Germplasm
Collecting and Transfer is a voluntary code developed by FAO and
negotiated by its Member Nations. The Code aims to promote the
rational collection and sustainable use of genetic resources, to
prevent genetic erosion, and to protect the interests of both donors
and collectors of germplasm. The Code is based on the principle of
national sovereignty over plant genetic resources. The Code
proposes procedures to request and/or to issue licenses for
collecting missions, provides guidelines for collectors themselves,
and extends responsibilities and obligations to the sponsors of
missions, the curators of genebanks, and the users of genetic
material. It calls for the participation of farmers and local
institutions in collecting missions and proposes that users of
germplasm share the benefits derived from the use of plant genetic
resources with the host country and its farmers.
3.2.3 The Manila Declaration Concerning The Ethical Utilisation of Asian Biological
Resources.
http://sunsite.wits.ac.za/iupac/reports/1996/6812andrews/manila.html
Developed at the Seventh Asian Symposium on Medicinal Plants,
Spices, and other Natural Products (ASOMPS VII) which was held
in Manila, Philippines from 2 to 7 February 1992 and was attended
by 283 scientists from 31 countries. This Declaration contains an
appendix containing a code of ethics for foreign biological sample
collectors and one with bioprospecting contract guidelines.
3.2.4 The Melaka Accord. This Accord carries the Manila Declaration forward by
calling for specific legislative steps at the national and regional levels.
http://sunsite.wits.ac.za/iupac/reports/1996/6812andrews/melaka.html
3.3 State Governmental Guidelines
3.3.1 US International Cooperative Biodiversity Groups (ICBGs)
http://www.fic.nih.gov/textonly/programs/icbg.html#Introduction
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This links to the general information page at the Fogarty

International Center, which administers the International Cooperative Biodiversity Groups (ICBG) Program. This program provides funding for investigating the relations between drug discovery, biodiversity conservation, and sustainable economic growth. Funding for this program has been provided by six components of the National Institutes of Health (NIH), the Biological Sciences Directorate of the National Science Foundation (NSF) and the Foreign Agriculture Service of the USDA. The cooperating NIH components are the Fogarty International Center (FIC), National Cancer Institute (NCI), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA) and the National Heart, Lung, and Blood Institute (NHLBI).

The main premise of the ICBG's is that "efforts to examine the medicinal potential of the earth's plants, animals and microorganisms are urgently needed, since enduring habitat destruction and the resulting diminishment of biodiversity will make it increasingly difficult to do so in the future. 40-50% of currently used drugs have an origin in natural products." The ICBG program is designed to guide natural products drug discovery in such a way that local communities and other source country organizations can derive direct benefits from their diverse biological resources. Benefit-sharing may provide clear incentives for preservation and sustainable use of that biodiversity.

3.3.2 Resources on Access, Intellectual Property and Benefit-Sharing Relevant to the ICBG Program

a. ICBG Resources

http://www.fic.nih.gov/textonly/programs/icbgresources.html

This page links to several useful documents on the web addressing intellectual property, access and benefit sharing, primarily in the Conventional on Biodiversity context, as well as academic articles.

b. Request for Applications for ICBG Funding

http://grants1.nih.gov/grants/guide/rfa-files/RFA-TW-03-004.html

This links to the most current request for applications (RFA) to the ICBG program. The RFA contains specific requirements and guidance on genetic resource access, benefit sharing, intellectual property ownership, biodiversity conservation, and economic development.

3.3.3 Belgian Co-ordinated Collections of Micro-organisms as co-ordinator (BCCM): Micro-Organisms Sustainable Use and Access Regulation (MOSAICC).
http://www.belspo.be/bccm/mosaicc/
http://www.belspo.be/bccm/mosaicc/docs/code.pdf
MOSAICC is a voluntary Code of Conduct. It is developed to facilitate access to microbial genetic resources (MGRs) and to help partners to make appropriate agreements when transferring MGRs, in the framework of the Convention on Biological Diversity (CBD)
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and other applicable rules of international and national laws. MOSAICC is a tool to support the implementation of the CBD at the microbial level; it can also serve as a model when dealing with genetic resources other than MGRs.
3.3.4 Australia
a. Commonwealth Public Inquiry into Access to Biological Resources in Commonwealth Areas
http://www.deh.gov.au/biodiversity/science/access/inquiry/index.html
The Inquiry's proposed scheme provides for an access permit and a benefit-sharing contract. Under the scheme, a party seeking access to biological resources in Commonwealth areas is required to apply for an access permit. Appropriate governmental agencies would review the request, and make a recommendation to the Minister for the Environment and Heritage to grant or refuse the permit. While the assessment is underway, the applicant would be required to negotiate, with the holder (or owner) of the biological resources, a benefit-sharing contract which covers the commercial and other aspects of the agreement. The contract would be based on a model contract developed and agreed by Governments, industry, Indigenous organisations and other stakeholders. The contract would only have effect if the Minister issues an access permit.
b. National Principles of Intellectual Property Management for Publicly Funded Research
http://www.nhmrc.gov.au/research/general/ipman.pdf
The purpose of developing the National Principles of IP Management for Publicly Funded Research is to assist researchers,

research managers and their research institutions, in ensuring that they have access to best practices for the identification, protection and management of IP, and therefore, to maximise the national benefits and returns from public investment in research. The intention of the National Principles is simply to improve the commercial outcomes from publicly funded research where a commercial outcome is appropriate. The National Principles are expected to evolve over time in the light of the experiences of the funding agencies, research institutions and researchers. Organisations may wish to develop their own detailed IP management strategies within the framework of these principles to best suit their particular environments and needs. The NHMRC recognizes that further consideration needs to be given to intellectual property issues in health and medical research involving indigenous people and communities, and

c. Bioprospecting and Indigenous Knowledge in Australia: Valuing Indigenous Spiritual Knowledge and its Implications for Integrated Legal Regimes; By John Hunter & Chris Jones

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http://ls.wustl.edu/centeris/Confpapers/Hunter-Jones%20final%20draft.htm

This paper discusses issues associated with the capacity of western law in understanding and protecting indigenous knowledge related to the bioprospecting of indigenous medical knowledge in an Australian context. More specifically the focus is upon indigenous spiritual knowledge. It is suggested that central to this project is the right of indigenous peoples in self-determination, self-identification and the right of verifying the authenticity of representations about such knowledge.

3.3.5 New Zealand, Ministry of Economic Development: Proposed Principles and Policy Objectives for Bioprospecting.

http://www.med.govt.nz/ers/natres/bioprospecting/discussion/bioprospecting-06.html#TopOfPage

This government document discusses policy and legal issues relating to bioprospecting in the context of New Zealand's economic development, while safeguarding associated environmental, social and cultural values,

by: establishing clear rules about access to biological resources; ensuring bioprospecting policy recognizes the principles of the Treaty of Waitangi; establishing mechanisms to facilitate the capture of benefits from bioprospecting activities; and gathering information on bioprospecting activities to ensure New Zealand can track the use of its biological resources.

3.4 Non-Governmental Organization Guidelines

3.4.1 Program for Traditional Resource Rights (PTRR)

http://users.ox.ac.uk/~wgtrr/

The Program for Traditional Resource Rights is dedicated to furthering the rights of all 'indigenous and local communities embodying traditional lifestyles' (as identified in the Preamble to the Convention on Biological Diversity). By acting as a base for information, research and publicity the Program aims to extend to Indigenous peoples and local communities knowledge of appropriate mechanisms for protecting the integrity of their knowledge and resources. The Program is a self-funded network affiliated with - and based at - the Oxford Center for the Environment, Ethics and Society (OCEES), Mansfield College, University of Oxford.

a. Guidelines for Equitable Partnerships in New Natural Products Development; Recommendations for a Code of Practice

By Dr Anthony B. Cunningham

http://users.ox.ac.uk/~wgtrr/cunning.htm

These Recommendations start from the premise that governments must accept responsibility for establishing or implementing national policies for the conservation and use of biological diversity, and proceeds by setting forth guidelines

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relating to licensing access, collecting responsibilities and procedures, responsibilities of sponsoring organizations, intellectual property and national development, and monitoring support.

b. The Global Coalition for Biocultural Diversity Covenant on Intellectual, Cultural and Scientific Resources: A basic code of ethics and conduct for equitable partnerships between responsible

corporations, scientists or institutions, and indigenous groups
http://users.ox.ac.uk/~wgtrr/gcbcd.htm
This Covenant is proposed as a model that can be tried in many parts of the world by many partners to “produce a new category that will replace IPR with a more powerful and decisive concept that, ideally, will catalyze the replacement of markets for temporary gain with trade based upon long term commitments that result in mutual advantages--turning businesses from being vanguards of destruction into equitable partners with local communities in the conservation of biological and cultural diversity”. According to the Covenant, the first concern of indigenous peoples is their right not to sell, commoditize or have expropriated from them certain domains of knowledge and certain sacred places, plants, animals and objects. All other elements of the Covenant are preconditioned by this basic right, which is considered a fundamental element of selfdetermination. Several of the basic principles focus on equity, non-exclusivity, confidentiality, economic diversification, and judicial recognition and registration of this agreement, followed by appropriate legal protection to enable the indigenous group to protect its knowledge and biogenetic resources.
c. Suggested Ethical Guidelines for Accessing and Exploring Biodiversity By Professor Anil K. Gupta; Based on a Pew Conservation Scholars Initiative to develop ethical guidelines to access Biological Diversity
http://users.ox.ac.uk/~wgtrr/gupta.htm
3.5 Private Companies and Industry groups
3.5.1 Bristol-Myers Squibb Company
http://www.bms.com/static/ehs/perfor/data/humanr.html#biopr ospect
3.5.2 BIO "Biotechnology's Foreign Policy", Carl B. Feldbaum, President Biotechnology Industry Organization June 10, 2002
http://www.bio.org/news/speeches/20020610.asp
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BIO is developing a set of principles for its members, most of whom are inexperienced in negotiating for access to biological resources in developing countries and especially with local authorities. The principles would include provisions for informed-consent and benefit-sharing. First and foremost that BIO member companies must respect the laws of nations and cultures of localities where they perform research.

3.6 Practical Pointers for Industry:

・Ethical codes and institutional guidelines occasionally impose legal obligations on certain groups and individuals, but more commonly are set forth as aspirational principles and "best practices" for the applicable members of the organizations to which they are intended to apply.

・Typical issues addressed in bioprospecting codes and guidelines include informed consent, confidentiality, benefit sharing, conservation, intellectual property ownership, and permissible use.

・There are, as can be seen above, variations—for example whether written or verbal agreements are considered best practice.

・As part of any bioprospecting negotiation, all parties should research applicable codes and guidelines, in additional to applicable laws and local customs and make an informed assessment of the role such codes and guidelines might serve.

・Organizations and institutions that have not adopted ethical codes and guidelines relating to bioprospecting and biodiversity research might consider initiating a process to develop them. A discussion of process issues for developing such codes and guidelines is discussed in the book *Biodiversity and Traditional Knowledge*, Sarah A Laird (ed), chapters 2 and 3 (Earthscan, 2002). It is important to consider both process and substance as integral elements of ethical codes and guidelines for bioprospecting.

4. Negotiation Issues

The more parties that are involved in a negotiation, and the greater the cultural differences of those parties, the more important it is to focus at the outset on the *process* of negotiation. The complexity of multiparty negotiation is significantly compounded by geographic and cultural differences. The articles and materials

below discuss a range of issues including: handling multiparty negotiations effectively, addressing cultural differences in negotiations and conflict, the potential role of "third party neutral" facilitators or mediators, so-called "best practices" of obtaining prior informed consent, and culturally influenced negotiation styles.

4.1 Interest-based Negotiation

http://www.colorado.edu/conflict/peace/example/fish7513.htm

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Summary by Tanya Glaser of "Getting to Yes: Negotiating Agreement Without Giving In" by Roger Fisher and William Ury (New York: Penguin Books, 1983).

In this classic text, which advocates interest based, win-win, negotiation over positional, win-lose, negotiation Fisher and Ury describe four principles for effective negotiation: 1) separate the people from the problem; 2) focus on interests rather than positions; 3) generate a variety of options before settling on an agreement; and 4) insist that the agreement be based on objective criteria.

4.2 Issues in multi-party complex negotiations

http://hbswk.hbs.edu/item.jhtml?id=3898&t=strategy

"Making the Most of Multiparty Negotiations" by Lawrence Susskind"

This article discusses the challenges of multiparty negotiation and the steps that can be taken to properly prepare, working effectively in coalitions, and managing group interactions.

4.3 Possible role of mediation/multi-party facilitation in the agreement process

http://www.triangleassociates.com/resource/artfac3.html

"Reflections: Breaking the Patterns" by Alice Shorett

This article discusses the role of process rules in public policy disputes, and has useful pointers for any multiparty negotiation process, especially the potential role of neutral third party facilitators.

4.4 Prior Informed Consent Processes

Although "prior informed consent" is one of the principles of the Convention on Biological Diversity, the CBD provides little guidance on how PIC should be obtained. The following papers and articles discuss the challenges and considerations, along with recommendations, on obtaining prior informed consent in different cultural (and inter-cultural) settings. This is an area where, although "best practices" are being sought,

the varying cultural contexts need to always be at the forefront of consideration. What is a “best practice” in one setting might be ineffective or inappropriate in others. However, a recurring theme is the to first focus on the process, and ensuring that it is an inclusive one.

4.4.1 “Politics, culture and governance in the development of prior informed consent and negotiated agreements with indigenous communities”

Joshua Rosenthal, Fogarty International Center, National Institutes of Health (September 4, 2003)

http://ls.wustl.edu/centeris/Confpapers/PDFWrdDoc/PICFinal.html

4.4.2 “The Philippines: A Bridle on Bioprospecting?” by Oscar B. Zamora

The Convention on Biological Diversity (CBD), now ratified by over 165 parties, reaffirms as international law that countries have national sovereignty over their biological diversity. Further, the Convention says

that access to genetic resources should be regulated by the parties along two principles: prior informed consent and mutually agreed terms. The CBD only lays down principles which individual countries have to translate into laws and regulations. The Philippines provides an example of how this might be done.

http://www.grain.org/publications/jun972-en.cfm

4.4.3 “Developing a Regime to Protect Indigenous Traditional Biodiversity - Related Knowledge” by Henrietta Fourmile-Marrie

Traditional biodiversity-related knowledge of biological resources can provide leads to industry researchers, saving valuable time and money in the research and development process. But it is also important for the long term economic security and sustainable development that Indigenous communities in Australia secure a stake and participate in this and any other industries based on Australia's biological wealth and its management. Indeed, for many of Australia’s Indigenous communities, their long-term sustainable economic development may also depend on their capacity to generate new intellectual property from their traditional knowledge; to create new products derived from their natural resources. Contractual means for protecting traditional knowledge, such as biodiversity contracts, non-disclosure clauses to protect certain kinds of information, and licensing agreements are important considerations.

http://wwwlaw.murdoch.edu.au/balayi/v1n1/fourmile.shtml

4.4.4 “Ethics and Practice in Ethnobiology and Prior Informed Consent with Indigenous Peoples, Regarding Genetic Resources” by Roger Chennells
Issues of intellectual property, prior informed consent, and benefit-sharing in the appropriation of indigenous knowledge are raised in the context of the San of Africa, and selected aspects of the benefit sharing agreement relating to Hoodia concluded on 24 March 2003, are discussed in the light of the general principles underlying the Biodiversity Convention.
http://ls.wustl.edu/centeris/Confpapers/ChennelFinalApril2003.htm
4.4.5 CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY Fifth meeting Nairobi, 15-26 May 2000 UNEP/CBD/COP/5/1. REPORT OF THE PANEL OF EXPERTS ON ACCESS AND BENEFIT-SHARING
Identifies the following key principles in the development of prior informed consent procedures:
(1) An applicant must supply sufficient information to allow for informed consent, including the best scientific and commercial information, and information regarding relevant social, cultural and environmental issues.
(2) The provider must be allowed to request further particulars.
(3) The information should be provided in a manner and language comprehensible to the provider.
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(4) Consent should be construed strictly.
(5) Prior informed consent of indigenous and local communities is dependent on clear recognition and protection of their rights, knowledge and innovation and practices. For this reason the development of sui generis legislation may need to be considered.
http://www.biodiv.org/doc/meetings/cop/cop-05/official/cop-05-08-en.pdf
4.5 Cross-cultural Communication Issues
4.5.1 “Mapping Cultures: Strategies for effective intercultural negotiations” by Chris Moore and Peter Woodrow
“Few 'maps' exist to describe how different cultures resolve conflict, often leading to misunderstanding and less than optimal agreements. This articles offers a framework for understanding cultural differences and negotiating accordingly.”
http://ccrweb.ccr.uct.ac.za/two/8_1/p04_mapping_cultures.html
4.5.2 Intercultural Conflict Management: A Mindful Approach

By Stella Ting-Toomey
After noting that intercultural miscommunication and misattributions often underscore intercultural conflict the author of this paper defines intercultural conflict as “the perceived or actual incompatibility of values, norms, processes, or goals between a minimum of two cultural parties over content, identity, relational, and procedural issues.” The author concludes by noting that “[w]hile the study of intercultural conflict is a complex phenomenon, understanding conflict along the individualismcollectivism continuum and the personal variation continuum (e.g., the independent and interdependent self across a spectrum) serves as the beginning step in understanding conflict variations among different clusters of cultures.”
http://www.personal.anderson.ucla.edu/richard.goodman/c4web/Mindful.htm
4.5.3 This web site describes the “Intercultural Conflict Style Inventory” (ICS), which is an assessment tool used in different settings to identify culturallylearned approaches for managing disputes in terms of direct or indirect strategies for resolving disagreements and emotionally expressive or restrained approaches for dealing with conflict. Combining these approaches results in four cross-cultural conflict styles: discussion, accommodation, engagement, and dynamic. Each of these styles has different implications for conflict resolution and communication in general.
http://hammerconsulting.org/ics_inventory.html
4.6 Practical Pointers
・Think about, discuss, and agree on the process of negotiation early, before focusing on the substance.
・Ensure and facilitate effective inclusion of all relevant “stakeholders” throughout the process.
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・Aim for a process that surfaces underlying interests, and consider, where culturally appropriate, interest based over positional negotiation.
・Consider face to face meetings whenever possible.
・Research, appreciate, and address cultural differences—which might relate to communication styles on the one hand, and difference in

values on the other, and often both.
• Minimize assumptions, maximize discussion.
• Research and learn from prior "case studies" regarding bioprospecting negotiation and especially prior informed consent.
• Take "best practices" into account.

5. Bioprospecting/Access and Benefit-Sharing Case Studies
NOTE: In all of the examples below, there is quite a body of literature on-line detailing all sides of the bioprospecting debate. For instance, Diversa has been in the news numerous times because of its landmark bioprospecting agreements with several organizations (Yellowstone, INBio, etc.). But, depending on the point of view of the reporter (or news organization) concerning bioprospecting, the bioprospecting activities of Diversa have been cast in either a positive or negative light. Because some viewpoints hold that ethical bioprospecting, with a level playing field for all parties involved in any benefit-sharing agreement, is impossible to achieve, the reports some news organizations
produce inevitably conclude that any company's bioprospecting activities are inherently inequitable toward indigenous and traditional communities.
5.1 Companies Engaged in Equitable Bioprospecting
5.1.1 Aveda
http://www.aveda.com
Long committed to business partnerships with indigenous peoples, the Aveda Corporation has gained the reputation of working to support indigenous rights, sustainable development, and biodiversity conservation. Aveda has long depended upon indigenous communities for sourcing the ingredients used in the company's line of cosmetics, beauty and skin care products. Aveda has recently shown its sensitivity towards indigenous intellectual property rights: the company recently abandoned its IndigenousTM trademark and beauty products line once it learned of the response by indigenous groups to the company's use of the term to market products. (Ironically, Aveda says it originally adopted the Indigenous term in order to draw attention and raise
awareness of values and wisdom held by indigenous peoples See Press Release at http://www.aveda.com/about/press/indigenous.asp).
5.1.2 Diversa
http://www.diversa.com
Diversa Corporation uses genomic technologies to discover and produce novel

compounds, particularly commercially valuable molecules with applications in the pharmaceutical industry, as well as enzymes and small molecules with the potential for 49
agricultural, chemical, or industrial applications. For example, Diversa has signed agreements for bioprospecting in micro-organisms in several countries including Costa Rica, Bermuda, Indonesia and Mexico, as well as a bioprospecting agreement with Yellowstone to research a commercially promising class of microorganisms known as thermophiles. However, Diversa's bioprospecting activities have attracted controversy; a
for example, a lawsuit was filed in response to the Yellowstone-Diversa bioprospecting agreement (see http://www.icta.org/legal/yellow.htm) although eventually it was resolved
at least in part. See also
http://www.diversa.com/presrele/2000/view_release.asp?id=20000419, as well as the notation on Yellowstone National Park below on this webpage.

5.1.3 InBIO (Instituto Nacional de Biodiversidad)

http://www.inbio.ac.cr/es/default.html

Established in 1989, InBIO was established to research the biological diversity of Costa Rica for its commercial potential in an ecologically sustainable manner. InBIO has been in the news numerous times (both positive and controversial accounts) for its innovative bioprospecting partnerships with pharmaceutical corporations and other companies. While some see InBIO as an innovative, enterprising research company, representing the
best of all worlds in ethical bioprospecting, critics of bioprospecting in general are suspicious of InBIO's activities and are quick to report negatively on any new research the organization undertakes (see http://www.grain.org for examples). InBIO has been both hailed and derided for its goals of commercializing biological resources combined with sustainable development and conservation.

5.1.4 Yellowstone National Park – Park Issues: Bioprospecting and Benefit-Sharing

Chapter 9 from *Yellowstone Resources and Issues 2004*

http://www.nps.gov/yell/publications/pdfs/handbook/ch9.pdf

This chapter reviews what thermophiles are and the making of the historic Yellowstone-
Diversa bioprospecting agreement (CREDA) in 1997, including also the controversy and lawsuit that followed. It reports that while the agreement between Yellowstone and

Diversa was upheld in the district court in 2000, the earlier court suspension on the agreement will remain in place until Yellowstone completes an Environmental Impact Study (EIS) – the result of which possibly being precedent-setting for all national parks interested in entering into bioprospecting activities with outside companies in the future.

5.1.5 Pharmaceutical Companies Partnered with International Cooperative Biodiversity Groups (ICBGs)

http://www.fic.nih.gov/programs/icbg.html#Continuing%20ICBGs

This site profiles each of the continuing ICBG programs currently in operation, in countries as diverse as Papua New Guinea, Vietnam, Laos, Panama, Madagascar, Uzbekistan, Kyrgyzstan, Nigeria, Cameroon, Argentina, Chile and Mexico. Within these

ICBGs, several companies are research partners and parties to the benefit-sharing agreements drafted by each ICBG to ensure equitable sharing of any benefits resulting 50

from research (e.g., Wyeth, Bristol-Myers Squibb, Diversa, Novartis, Dow Agrosciences, and Phytomedics, Inc.). While none of these companies, on their own websites, specifically highlight their participation in the ICBG Program, many of the companies listed do feature web pages citing their commitment to sustainable development, human

rights, providing access to affordable health care and other global concerns.

5.1.6 The Body Shop

http://www.thebodyshop.com/web/tbsgl/values.jsp

The Body Shop has long had the reputation of providing a fair and equitable market for small communities and indigenous groups worldwide, since The Body Shop uses natural, sustainably grown ingredients as source ingredients in their cosmetics, hair, skin and beauty care product lines. The Body Shop also lists a variety of other causes they support, either directly or indirectly, on their website. While some investigative reports by journalists in the early 1990s attempted to show that The Body Shop is not as committed as it purports to be to the small communities from which it sources its raw materials, The Body Shop has withstood the test of time and is doing well as a business today, grounded in the same principles upon which it was founded in the 1970s. (Much of the criticism towards The Body Shop seems to have been directed at its using a “green consumer” message to promote sales and to distinguish itself from other businesses, while at the same time expanding rapidly worldwide, not unlike Starbucks or any other typically “self-interested” corporation on the market. This criticism may have stemmed

just as much from sentiments that The Body Shop's primary customers are relatively affluent individuals (living in the developed world) who believe they are making a big difference in the world by simply buying The Body Shops' beauty products).

5.2 Case Studies on Biodiversity

http://www.biodiv.org/doc/case-studies/default.aspx

This webpage, through the Convention on Biological Diversity website, lists a number of case studies that provide models for designing access to genetic resources and benefitsharing schemes. Several of the publications outline the progress of the ICBGs, highlight

various partner-companies (such as pharmaceutical and agribusiness corporations), including one early publication reporting on the "new" Yellowstone-Diversa Agreement in 1997. While many of the reports are at least few years old, together they provide a chronology of thought, reflections, and recommendations for the rapidly-evolving set of issues connected to access and benefit-sharing, and for which there are no "one-size fits all" or simple answers.

5.3 SUMMARY/POINTS TO CONSIDER:

・For every positive report about a company's bioprospecting activities on-line, it is highly likely that there will be negative report about the very same activity. These reports, both positive and negative, must be taken in view of the larger, ongoing debate on bioprospecting – realizing that there are rigid viewpoints on both sides that will use any example of a company's bioprospecting activity to support *any* viewpoint about bioprospecting. Therefore, it is up to you, the

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reader, to critically assess both the report itself of any bioprospecting activity as well as the source of the report itself. An website with an activist (or corporate) agenda, for example, may be more likely to have a strongly biased viewpoint on bioprospecting (either positively or negatively) than would a website that simply reports the news in a balanced fashion.

・Whether a company's bioprospecting activities are ethical and sufficiently concerned about the issues of access to genetic resources and benefit-sharing for all involved can only be assessed by critically evaluating the kinds of benefits being provided, and by being realistic in what kinds of benefit-sharing schemes any company can set up. For example, some critics of bioprospecting cite the unfairness of, say, a royalty rate of only 3% going to a community that was involved in identifying leads for a new drug or botanical supplement – but without mentioning that a royalty rate of 3% is actually a typical rate of return for

any inventor who agrees to a company "developing" their idea into a finished product (the usual royalty rate is anywhere between 1% and 5%, depending on the terms of the agreement). For royalty rates to be any higher usually implies that the cost and responsibilities for developing the final product are correspondingly shared by the parties as well (for example, the case of the Sarawak Government and a national pharmaceutical company, both assuming the costs of developing a new anti-AIDS drug, but then also expecting to split the royalties from any new anti-AIDS drug 50-50).

・Because the idea of ethical bioprospecting is a relatively new one, and is viewed as a way to redress decades (if not centuries) of legal wrongs, there are many who are downright suspicious that ethical bioprospecting can actually work – and there are many who believe that it is simply one more way that a company claims (falsely) it acting responsibility as a corporation. The only way we will be able to know whether or not this new paradigm for bioprospecting will work, and even enter the mainstream of corporate business practices, will be to watch for and critically evaluate the kinds of benefit-sharing arrangements that companies create over time – and to allow time to pass before fully judging whether or not a specific benefit-sharing scheme actually works. Hopefully in another 5 to 10 years there will be that many more access and benefit-sharing arrangements in place between companies and traditional communities that can be evaluated for their ability to support ethical and equitable bioprospecting research activities.

・The kinds of benefits that are provided by a company to the other parties (usually the "source" or "host" communities, groups or countries) are often tailored to what the other party has negotiated for, and do not always take the form of benefits that someone outside of the arrangement would expect to see as a benefit. In many of the ICBG (drug discovery) benefit-sharing agreements, for example, short-term and medium-term benefits are included as part of the benefit-sharing scheme with the host countries, institutes and communities because it is understood that the long-term benefits outlined in the agreements are not likely to be realized (because of the nature of drug discovery research in general). Other kinds of benefits, such as capacity-building, technology transfer, educational training, community outreach, community economic development, and other benefits are included in the benefit-sharing scheme, as well as the more "traditional" benefits (such as royalties and monies placed into trust funds).

・It is important to keep in mind that much of what companies are doing, when they attempt to implement access and benefit-sharing arrangements as recommended

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by the Convention on Biological Diversity, is trying to translate these bioprospecting ideals to real-world bioprospecting research projects. It may turn out that some current ideas for benefit-sharing, while looking good on paper, may be practically and logistically more difficult to implement than currently understood and for reasons currently unforeseen. Part of the process of creating "best bioprospecting practices" worldwide will be the usual trial and error; hopefully the reports of "what works" in practice will guide future bioprospecting activities and keep other companies from making similar mistakes when drafting their own benefit-sharing arrangements. Until more time has passed and more benefit-sharing arrangements have been fully operationalized, we simply will not know which of these will meet with greater success and "win-win" for all parties involved.

6. Types of Access and Benefit Sharing Agreements

6.1 Background: There are numerous agreements that may be employed when bioprospecting activities are contemplated. These agreements serve various purposes, which include securing necessary governmental approvals, sharing benefits with the traditional communities or the national park where samples are collected, protecting intellectual property interests, and protecting the parties from legal liabilities.

The basic agreements are:

Collaboration/Partnership Agreements: These agreements typically describe the total sum of activities that will be occurring, and are useful when a mutual understanding is needed concerning the roles and activities of each of the participating organizations and entities (including traditional communities and governments) that will be performing bioprospecting activities.

Permits: Permits are required by many governmental agencies prior to the collection of materials in territories within their jurisdiction.

Licenses: Once a potentially viable property is located, a license agreement is entered into between the owner of the intellectual property ("licensor") and the entity that desires

to use the intellectual property ("licensee") to govern how the property is to be used and (when appropriate) to specify compensation to the owner for the use. Sometimes, license terms are embedded within other agreements, such as a collaboration agreement or a material transfer agreement, in anticipation of discovering viable properties.

Material Transfer Agreements ("MTAs"): Material Transfer Agreements are used when

physical samples, such as biological or chemical compounds, are exchanged between two parties. Generally, MTAs are entered into to protect the intellectual property rights of the
provider and to limit the liability of the provider with respect to the recipient's activities,
although MTAs may also contain license terms governing the recipeint's commercial use of the provided material.
Research and Development Agreements: These agreements related to the terms for funding, and performing, research projects and address the relationships between the party funding the research and the party(ies) performing the research.
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6.2 Types of Agreements.
6.2.1 Sample Agreements (excluding governmental permits).
(i) World Intellectual Property Organization: Traditional Knowledge and Cultural Expressions Contracts Database.
http://www.wipo.int/tk/en/databases/contracts/summaries/index.html
This database contains many types of model agreements and actual agreements related to bioprospecting. It includes material transfer agreements, licensing agreements, benefit-sharing agreements, collaboration agreements and research agreements. The database collection is an ongoing effort so this database will continue to expand.
(ii) National Institutes of Health, National Cancer Institute: Standard Forms and Agreements. http:ttb.nci.nih.gov/forms.html.
In recent years, the U.S. National Cancer Institute has become involved the terms related to bioprospecting for materials used in its studies. Several standard agreements on this website relate to bioprospecting, including the Cooperative Research and Development Agreement (CRADA), which is used when U.S. government owned materials (whether an invention at NIH or plant samples collected in a National Park) are developed for commercialization, as well as material transfer agreements and a Letter of Collection to establish an understanding with a foreign country on how its materials will be used for NCI research.
(iii) Outline of Issues to Address and Language to Consider in a Biodiversity Prospecting Agreement Chapter 10 and Appendix 10.1, from *Biodiversity and Traditional Knowledge: equitable*

partnerships in practice, by Michael A. Gollin.
http://www.rbgkew.org.uk/peopleplants/manuals/biological/annexes2.htm
This document contains an outline of the contract terms that should be considered for inclusion in agreements related to bioprospecting, and a sample agreement with detailed terms and language that covers most issues associated with collecting materials in a foreign country, including sharing commercialization revenue with the host country.
(iv) Exploiting South Africa's Horticultural Potential: The National Botanical Institute and Ball Horticulture
http://www.biowatch.org.za/Benefit_sharing.doc
This paper discusses three case studies of bioprospecting in South Africa.
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6.2.2 Sample Governmental Permits/Requirements.
(i) Permits: Most countries and many local governmental entities have permits that must be obtained prior to the collection of materials from its territories. Many include questions concerning how the fruits of commercialization will be shared with the country and its citizens. The terms of collection permits vary widely. A few sample permits requiring explanations of benefit-sharing include:
(a) Parks and Wildlife Commission of the Northern Territory, Australia: Application for a Permit to Undertake Scientific Research on Wildlife. http://www.nt.gov.au/ipe/pwcnt.
(b) Environmental Protection Agency, Guyana: Application for Scientific and/or Commercial Research on Biodiversity in the Co-Operative Republic of Guyana.
http://www.epaguyana.org/downloads/ApplicationBiodiversityResearchGuyana.pdf
(c) U.S. National Parks Service: Benefit Sharing Agreements. www.nature.nps.gov/benefitssharing/contents.htm (includes sections discussing legal authorities and a FAQ).
(ii) Governmental Requirements concerning Protection of Biotechnological Inventions.
World Intellectual Property Organization: Information Provided

by WIPO Member States concerning Practices Related to the Protection of Biotechnological Inventions, April 30 to May 3, 2001.
http://www.wipo.int/documents/en/meetings/2001/igc/pdf/grtkfic1_6.pdf
As part of ongoing research, WIPO conducted a survey of member states with a variety of questions related the scope of patent protection available in the state over animals, plants, and microorganisms. This survey is useful for understanding the legal limits of intellectual property ownership in various countries which, in turn, limit the terms of agreements entered into for bioprospecting in the states' territories.
6.2.3 Articles concerning the structure/types of Bioprospecting Agreements.
(i) Gollin, M.A., "Elements of commercial biodiversity prospecting agreements," chapter 10 in *Biodiversity and Traditional*
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Knowledge: Equitable Partnerships in Practice, edited by Sarah Laird. (Earthscan 2002).
This is a useful summary of the various types of agreements and when they should be used. It is a practical guide with clear explanations and several case studies. It compares biodiversity prospecting contracts to other types of contractual arrangements, and provides the core elements of biodiversity prospecting contracts. Examples of language from a range of negotiated contracts are provided to indicate current options agreed upon, in an annex available on the web.
(ii) Gollin, M.A., "Outline of issues to address and language to consider in a biodiversity prospecting agreement," annex 10.1 in *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*, edited by Sarah Laird. (Earthscan 2002), See file://www.rbgkew.org.uk/peopleplants/manuals/biological/annexes2.htm; Available at: www.rbgkew.org.uk/peopleplants/manuals/biological/annexes2.htm
(iii) The WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) compiled an on-line,

searchable database of biodiversity-related Access and Benefit-Sharing Agreements, Available at http://www.wipo.int/tk/en/databases/contracts/summaries/index.html

(iv) Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice, Chapter 10, edited by Sarah Laird
This is a useful summary of the various types of agreements and when they should be used. Practical guide with clear explanations and several case studies.

(v) The Global Biodiversity Institute/International Institute of Tropical Agriculture: Training Course on Biodiversity, Biotechnology, and Law. http://www.aaas.org/international/africa/gbdi/GBDI-Ibadan.pdf
Module II of this training course, developed for teaching in West Africa in March 2000, discuses "The Fundamentals of Bioprospecting Negotiations", which includes a description of the various types/purposes of agreements, issues to consider during the drafting and negotiation of agreements.

(vi) Bioprospecting in Practice: A Case Study of the Suriname ICBG Project and Benefits Sharing under the Convention on Biological Diversity. http://www.biodiv.org/doc/case-studies/abs/cs-abssr.pdf
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This article dissects one particular negotiation, identifying the various parties, the expectations and needs of the parties, and the content/implementation of the resulting agreement.

7. Important Contractual Terms to Consider

This section contains resources on and examples of typical terms that have been included and should be considered in bioprospecting/ABS agreements. Included with each of the listed sub-sections are links to information that define the terms, provide an analysis or discussion of the terms, or include actual agreement language. Most online resources discuss bioprospecting agreements in their entirety so the listed resources are likely to provide information on many of the listed subsections.

The contractual terms can be considered to fall into the following main categories:

・Access and collection – materials, traditional knowledge, scientific information, etc.

・Type of relationship – exclusive vs. nonexclusive, number of parties involved,

the roles and responsibilities of each of the involved, etc.
• Commercialization –steps to be made towards commercialization and limitations.
• Financial benefits – royalties and fees, payments from and to whom, products on which payments will be made, etc.
• Non-financial benefits – conservation, training, education, etc.
• Intellectual property – what rights are attainable, who will secure those rights, who will own those rights, and what rights are retained.

7.1 Role and responsibilities

In any commercial agreement there are key roles and responsibilities to consider in bioprospecting/ABS agreements. These roles and responsibilities range from who will identify and collect samples to who will commercialize any promising products.

7.1.1 Guidelines for Equitable Partnerships in New Natural Products Development

Recommendations for a Code of Practice (Conclusions of the Workshop on Drug Development, Biological Diversity and Economic Growth, National Cancer Institute of the US National Institutes of Health, Bethesda, Maryland, 1991)
http://users.ox.ac.uk/~wgtrr/cunning.htm
Compiled by Dr. Anthony Cunningham, these Guidelines list a Code of Practice, or ethical protocols for researchers, sponsoring organizations, governments and other parties involved in the natural product development process. The Code includes procedures covering collection, licensing, intellectual property concerns, and evaluation and monitoring of biodiversity.
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7.1.2 The Conservation Finance Guide on Bioprospecting – a joint project of the Conservation Finance Alliance

http://guide.conservationfinance.org/chapter/index.cfm?Page=5
Discusses the design of bioprospecting agreements and provides a worksheet to help set out the various terms and responsibilities involved in those agreements.

7.2 Common Features

7.2.1 IUPAC - "General features of contracts for natural product collaborations"

http://sunsite.wits.ac.za/iupac/reports/1996/6812andrews2/index.html
This technical report by IUPAC provides a summary of agreement features and discusses sample terms.

7.2.2 IUPAC – "General features of contracts for natural product

collaborations"
http://sunsite.wits.ac.za/iupac/reports/1996/6812andrews2/agreement.html
This technical report by IUPAC provides an agreement template to show what is included in a typical collaborative agreement, including rights, responsibilities, and benefit-sharing provisions.

7.2.3 WIPO - Traditional Knowledge and Cultural Expressions – Contracts Database
http://www.wipo.int/tk/en/databases/contracts/summaries/index.html
This database provides on-line several examples of model agreements, as well as actual agreements, employed to protect the intellectual property concerns of the parties involved
in collaborative arrangements. Each of the contracts provides an example of agreed upon
roles and responsibilities for each of the involved parties. The WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore has worked over the past several years to bring greater attention to the issue of intellectual property rights
protections for communally-held knowledge, resources, expressive cultural forms, and other forms of cultural property not protected by conventional (Western) intellectual property law systems.

7.2.4 Global Biodiversity Institute/International Institute for Tropical Agriculture Biodiversity, Biotechnology, and Law Training Course for West Africa
Module II: The Fundamentals for Bioprospecting Negotiations
http://www.aaas.org/international/africa/gbdi/mod2a.html
A course primarily designed those in developing countries, this module provides an overview of the issues that need to be addressed in establishing a contractual agreement
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for benefit sharing. Bioprospecting activities, the kinds of agreements commonly used to ensure benefit-sharing, points for negotiation, discussion topics and the general principles
underlying the construction of a contractual benefit-sharing agreement are also outlined.

7.3 Access to materials (genetic/biological)

7.3.1 Andean Pact: Common System on Access to Genetic Resources
http://users.ox.ac.uk/~wgtrr/andpact.htm

Outlines for all member signatory countries of the Cartagena Protocol the objectives, aims, scope, principles and procedure for governing access to genetic resources in keeping with the provisions of the Convention on Biological Diversity. Unofficial UN translation from Spanish to English.

7.3.2 Micro-Organisms Sustainable Use and Access Regulation: International Code of Conduct (MOSAICC)

http://www.belspo.be/bccm/mosaicc/docs/code.pdf

From the Belgian Co-ordinated Collections of Micro-organisms (BCCM), penned by Philippe Desmeth at MOSAICC. Lists terms of agreement and model documents, including a model Material Transfer Agreement and a Prior Informed Consent application form in Section II.

7.3.3 Commonwealth Public Inquiry into Access to Biological Resources in Commonwealth Areas

http://www.deh.gov.au/biodiversity/science/access/inquiry/index.html

Extensive document discussing proposed scheme for regulating and monitoring access to biological resources in Australia. The inquiry report concludes that there is no mechanism in place for access to genetic resources that is consistent nationally, and provides recommendations for future legislation to correct this.

7.3.4 The Model Law Of The Organization Of African Unity On Community Rights And On The Control Of Access To Biological Resources (Third World Network)

http://www.twnside.org.sg/title/oau-cn.htm

A Model Law created to guide African nations in drafting and passing legislation concerning access to genetic resources.

7.3.5 Status and Trends in Access to Genetic Resources and Traditional Knowledge in Sri Lanka

http://www.biodiversityasia.org/books/abs/Chapter%2013.pdf

This paper reviews recent conservation and sustainable use legislation passed in Sri Lanka that is designed to protect genetic resources, while critically appraising its ability to fulfill the objectives of the Convention on Biological Diversity (CBD). Both the strengths and weaknesses of the new legislation are highlighted, with recommendations for increased stakeholder participation in the national access and benefit sharing process.

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7.4 Collection process and documentation

7.4.1 The FAO Global System: The International Code of Conduct for Plant

Germplasm Collecting and Transfer
http://www.fao.org/ag/agp/agps/pgr/icc/icce.htm
Provides guidelines (primarily to governments) for permit issuance, monitoring, and regulation of the collection and transfer of germplasm. The Code is based on the principle of the CBD that nations exercise sovereign rights over genetic resources and therefore have the right to implement and enforce rules that uphold this right. Also includes a list of terms; responsibilities of governments, collectors, sponsors, curators and users; and evaluation and monitoring the observance of the Code itself.
7.4.2 Manila Declaration (1992)
Seventh Asian Symposium on Medicinal Plants, Spices and Other Natural Products (ASOMPS VII)
http://nimura.tripod.com/manila.htm
Recommendations are provided regarding research, collecting and harvesting of plants and natural products. Many of the tenets formulated here later influenced the Philippines Biodiversity legislation passed in 1997.
7.4.5 People and Plants Online – Collecting Programmes
Exclusive and Non-Exclusive relationships
http://www.rbgkew.org.uk/peopleplants/dp/dp2/issues.htm
Provides a basic overview of the issues involved in conducting ethical ethnobotanical research, including intellectual property rights and the use of indigenous knowledge. Also includes a glossary of terms and recommendations for ethical collecting, documentation, benefit-sharing and protection of indigenous intellectual property and traditional knowledge.
7.5 Types of benefits: ABS agreements can provide for a range of benefits, including financial (fees, royalties), conservation, and capacity building.
7.5.1 International Conservation Union (IUCN)
Sharing the Benefits from Genetic Resource Use (Biodiversity Brief 3)
http://www.iucn.org/themes/wcpa/pubs/pdfs/biodiversity/biodiv_brf_03.pdf
This concise publication reviews the use of royalties and trust funds to generate and manage monetary benefits directed to communities participating in bioprospecting arrangements. Additionally, short-term and medium-term benefits to communities, as well as long-term benefits are discussed as equitable measures for communities' providing access to genetic resources.
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7.5.2 Implementing IPR and Benefit-Sharing Arrangements: Experiences in the

University of Illinois at Chicago–Vietnam-Laos ICBG
http://www.uic.edu/pharmacy/research/icbg/Paper-Proceedings-JBAsymposium.pdf
This article describes the establishment of Trust Funds as well as a royaltysharing scheme (under the Memorandum of Understanding) to govern benefitsharing among all of the parties involved in the UIC-based-Vietnam-Laos ICBG.
Also candidly explains the progress and obstacles in implementing short-term, medium-term and long-term benefits to the host countries and communities over the course of the ICBG project.

7.5.3 Equitable Sharing of Biodiversity Benefits: Agreements on Genetic Resources
http://www.fic.nih.gov/programs/oecdub.html
Authored by Joshua Rosenthal, this paper discusses all aspects of benefit-sharing arrangements, including: (1) the kinds of benefits that may be derived from bioprospecting agreements; (2) who should receive benefits; and (3) negotiations and the structure of the benefit-sharing agreement. While this report dates back to 1996 (and is in large part based on the provisions of the CBD and subsequent Conferences of the Parties), the basic issues it identifies are still as pressing and true in the present day.

森岡論文

論説

遺伝資源のアクセスと利益配分の実情と課題－国際的 動向からみた日本への示唆－

Access and Benefit-sharing of Genetic Resources -Proposal for Japanese Industries from International Trend of the Convention of Biological Diversity -

森岡　一

はじめに

遺伝資源を巡る国際問題は、地球環境の保全という国際的な運動のもとで『気候変動に関する国際連合枠組条約[3]』とともに地球上の遺伝資源保全を目指した『生物多様性条約[4]』で合意に達した。生物多様性条約の第一条には三つの目的が規定されている。第一の目的は生物の多様性の保全である。第二の目的はその構成要素の持続可能な利用であり、第三の目的は遺伝資源の利用から生ずる利益の公正かつ衡平な配分である。遺伝資源は多くは資源国といわれる開発途上国に存在し、それを利用するのは利用国と呼ばれる先進国であるため、遺伝資源の保全にはいわゆる南北問題と呼ばれる資源国と利用国の間の経済格差問題が色濃く反映されている。資源国と利用国の間の遺伝資源を巡る問題の解決に向けた妥協点を見出すために、生物多様性条約の前文に『諸国が自国の生物資源について主権的権利を有することを再確認し』という文言が挿入された。遺伝資源にはそれが存在する国の主権的権利があるということになる。これは地球規模での環境保護という目的からかけ離れている。主権的権利の経済的効果として、第三の目的の利益の公正かつ衡平な配分が決められ、本条約に基づくさまざまなルールが作られることになったが、いまだに資源国と利用国が合意するようなルールができたわけではない。

本稿では、生物多様性条約における利益配分に関する国際政治と実務でのさまざまな議論を概観し、現在の状況と将来の方向性について論じる。さらに、私見であるが、利用国の産業界への実務的な提案として、利用と利益配分の新しい仕組みを提案する。

遺伝資源を巡る世界のルールの変遷

3 外務省；『気候変動に関する国際連合枠組条約』、http://www.mofa.go.jp/mofaj/gaiko/kankyo/jyoyaku/clm_cnv.html。

4 外務省；『生物多様性条約』、http://www.mofa.go.jp/mofaj/gaiko/kankyo/jyoyaku/bio.html。

生物多様性条約の第三目的である遺伝資源の利用から生ずる利益の公正かつ衡平な配分に対する議論は、本条約の発効後、資源国と利用国の間で議論されてきた。ここで注意したいのは、本条約の加盟国は 2012 年 2 月現在 192 カ国と欧州連合となっているが、大部分は資源国である点である。利用国は日本、欧州であり、そのほかに資源国と利用国の両方の性格を持つカナダとオーストラリアがある。最大の利用国である米国は加盟していない。国際条約の議論の中で、圧倒的な数の資源国と少数の利用国の間の議論は、多数派の資源国の賛成を得られない限り合意に達するのは困難である。利益配分に関する問題は現在も続いており、多数派資源国の要求がますます先鋭化・拡大傾向になっている。

遺伝資源を巡る問題は経済問題として資源国は取り上げ、多くの国際フォーラムに議論が拡大している。国連機関である世界知的所有権機関（WIPO）[5]では、遺伝資源に関連する発明特許にその遺伝資源の出所開示を求める取組みと、遺伝資源に関連する伝統的知識の取り扱いについて各政府間で協議が継続している。世界保健機構（WHO）[6]では、インドネシアの高病原性 H5N1 型鳥インフルエンザウイルス標本を WHO 世界インフルエンザサーベイランスおよびレスポンスシステム（GISRS）に提供することを 2007 年以来拒み続けている問題があり、WHO 世界インフルエンザサーベイランスおよびレスポンスシステム（GISRS）のルールの見直しに発展した。インドネシアの主張は、インドネシアで分離された高病原性 H5N1 型鳥インフルエンザウイルスにはインドネシアの主権的権利が及ぶとする生物多様性条約を根拠とするものであった[7]。植物新品種保護国際同盟（UPOV）[8]では、農業用遺伝資源について国際的な取り決めである『植物の新品種の保護に関する国際条約[9]』とその一部である『食料農業植物遺伝資源条約(ITPGR－FA)[10] 』が有効であるが、その中で農業用遺伝資源へのアクセスと利益配分について議論がなされ、有効なメカニズムが構築された。国際貿易機関（WTO）[11]では、遺伝資源と知的財産の間で先鋭的な議論が繰り広げられている。これは利用国が主張する資源国での知的財産権保護と、資源国が主張する遺伝資源の利益配分が真っ向から対立する問題であるからである。資源国は、先進国側に傾いた WTO を資源国側に有利なように変更したいという意思が非常に強いことによる。生物多様性条約に加盟していない米国が WTO を主導していることが、資源国に

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5 世界知的所有権機関：World Intellectual Property Organization：WIPO と略、http://www.wipo.int/about-wipo/en/。

6 世界保健機構: World Health Organization:WHO と略；http://www.who.int/en/。

7 森岡一;『インドネシアの高病原性鳥インフルエンザウイルス標本提供拒否問題が提起している課題』、*知財ぷりずむ*、**5** (57)、2007/6、森岡　一；『 H5N1 型鳥インフルエンザウイルスに対する私有権と公共の利益』、*知財ぷりずむ*, **7 (78)**, 2009。

8 植物新品種保護国際同盟：Union internationale pour la protection des obtentions végétales：UPOV と略；http://www.upov.int/portal/index.html.en。

9 植物の新品種の保護に関する国際条約 : INTERNATIONAL CONVENTION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS of December 2, 1961, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991, http://www.upov.int/upovlex/en/conventions/1991/act1991.html。

10 食料農業植物遺伝資源条約：The International Treaty on Plant Genetic Resources for Food and Agriculture：ITPGR-FA と略； http://www.planttreaty.org/content/texts-treaty-official-versions。

11 国際貿易機関：World Trade Organization：WTO と略；http://www.wto.org/。

とって不利と感じさせているのが原因でもある。国際フォーラムでの問題の中心は南北問題であるため、ますます拡大するのみであり、解決への道筋は見えてこない。先進国は、遺伝資源は公共の共有財産であると考えているが、資源国は遺伝資源に資源国の主権的権利があると考えている。先進国は、知的財産権は技術に対する経済的保護であると考えているが、資源国は、伝統的知識等は新たな経済的権利であるとして譲らない。先進国は、知的財産権の保護・法執行の強化を資源国に求めているが、資源国は、技術の保護強化には徹底的に抵抗し、強制実施権の発動で対抗しようとしている。

生物多様性条約の第八条第 j 項で伝統的知識に関する利益配分が示されている。しかし、伝統的知識は知的財産に関連する事項であると考えられているので、知的財産を取り扱う国際的機関である WIPO で議論しなければならないし、WIPO で決めた取り決めと生物多様性条約の取り決めが一致していなければ混乱を招くことになる。しかし、両フォーラムの考え方や加盟国勢力が異なることから、両フォーラムの意見がかならずしも一致するとは限らない。米国は生物多様性条約には加盟していないが、WIPO では中心的役割を担っている。ちなみに 2012 年 10 月に開かれる WIPO 総会において、伝統的知識の取り扱いについて議論される予定になっている。

フォーラム間での意見の不一致現象が多くのフォーラムで問題を起しており、なかなか合意に至らない状況となっている。多数決あるいは全員一致で決するこれらのフォーラムでは、強いリーダシップがないため、各国の意向をすべて盛り込んだ奇妙な条文案が作成されることがたびたび見られる。このような状況を改善するために多くの努力がなされているが、その多くは、利害あるいは意見の一致した国が新たなフォーラムを創る傾向にある。

しかし、既存のフォーラムとの調整がますます困難になることは明らかであり、このような状況は今後も続くと考えられる。新たな考え方に基づく取組みが求められている。解決するための基本精神は WIN-WIN であると強く主張したい。単なる合意のための妥協ではなく、目的に向かうお互いの共通認識と熱意が根底になければならない。国際フォーラムはますます複雑、多様化する傾向が強く、この基本精神の下で各条約間の調整を行なわなければ前進はない。

ボン・ガイドラインと名古屋議定書

このような国際フォーラムでの混乱が続いていて、生物多様性条約内でも利益配分を巡る資源国と利用国の間の論争は現在に至っても続いている。各条約の枠組み内では、条約に書かれている課題を解決するため、多くの下部専門委員会が構成され、各国代表の専門家が議論を続けるのが通常のスタイルである。そして定期的に開かれる締約国会議（COP）にさまざまな案が提案され、議決される。利益配分に関する議論も COP4(1998 年)から始まり、アクセスと利益配分に関する作業部会が COP5(2000 年）で設置され、ようやく COP6(2002 年)でボン・ガイドライン [12]という形を得て採択された。利益配分に関する実行性あるルールができたのは、条約締結

12 一般財団法人バイオインダストリー協会；『ボン・ガイドライン』，
http://www.biodic.go.jp/cbd/pdf/6_resolution/guideline.pdf。

から 10 年に月日が流れたことになる。当然、その 10 年間はルールがないため、混乱があったことは容易に想像できる。ボン・ガイドラインは、遺伝資源へのアクセスと利益配分について当事者間が相互に合意する条件を契約書としてまとめるためのガイドラインである。このガイドラインは当事者間の任意によるものなので、法的強制力を持たない。当事者として、資源国の政府機関は、アクセスと利益配分に対する対応窓口を設置し、国内法や施行則を定めることが求められている。もう一方の当事者である利用国の利用者は、事前の情報に基づき資源国の関係者および政府に同意をもらわなければならない。これを事前同意（PIC）[13]という。その後、当事者間の契約交渉がまとまれば、相互合意に基づき契約等を締結し、利益配分の方法を決定する。この段階を相互に合意する条件（MAT）[14]という。

ボン･ガイドラインが合意され実行段階に入ったにもかかわらず､資源国の中にボン･ガイドラインは法的強制力を持たないため､利用者が契約通り実行しているかどうかわからないという不満が高まった。利用国側は一貫してボン・ガイドラインの実行を優先することを主張したが、多勢な資源国の主張に押し切られ、ボン・ガイドラインの実行途中から、強制力のある新しいルールの作成を検討することになり、第 10 回締約国会議（COP10）に議決する予定が決定された。専門委員会が構成され、そこで議論が COP10 直前までなされた。しかし、両サイドの主張に歩み寄りはなく合意は困難という予想であったが、議長の努力により、2010 年 10 月『生物の多様性に関する条約の遺伝資源へのアクセスおよびその利用から生じる利益の公正かつ衡平な配分に関する名古屋議定書』[15] (いわゆる名古屋議定書)が採択された。名古屋議定書の主な論点と結論は次のようになっている。

遺伝資源と派生物については､資源国は遺伝資源の利用によって生じる派生物も利益配分の対象とするよう要求しているが､生物多様性条約の文言では遺伝資源の利用から生じる利益となっているため、議定書では第二条で派生物が限定された [16]。利用国のチェックポイントについては､資源国は､利用国での遺伝資源の利用状況をモニターする措置を取ることを要求しているが、一つ以上のチェックポイントを指定し、必要な措置を取ることになった。ただし、利用国が反対していた特許申請時の出所開示などの具体的チェックポイントは示されなかった [17]。遡及適用については、資源国は生物多様性条約発効以前に取得された遺伝資源や、出所のわからない遺伝資源にも名古屋議定書を適用すべきであると主張した。アフリカグループが強く主張し、大航海

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13 遺伝資源へのアクセスには、遺伝資源を提供する契約締結当事者による、情報提供に基づく事前同意（Prior Informed Consent：PIC と略）が前提条件である。

14 相互に合意する条件（Mutually Agreed Terms：MAT と略）；当該遺伝資源の提供者と利用者の双方の合意に基づいて行われなければならない。具体的には、資源提供国の法令と当事者間の契約によって定められる。

15 外務省；『生物の多様性に関する条約の遺伝資源へのアクセスおよびその利用から生じる利益の公正かつ衡平な配分に関する名古屋議定書』、http://www.mofa.go.jp/mofaj/gaiko/treaty/shomei_72.html。

16 第二条：派生物；“Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity と定義された。

17 第十三条：チェックポイント；“To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:(a) The designation of one or more checkpoints,（以下省略）”となった。

時代あるいは植民地時代に資源国から欧州に持ちこまれた遺伝資源の取り扱いを明確にしたいという要求がある。しかし、国際条約では条約発効以前には条約を適用しないので、議定書には遡及適応は盛り込まなかったが、地球規模の多国間利益配分メカニズムを検討することで妥協した。その結果、地球規模の多国間利益配分の仕組みについては、議論されないまま議定書の第十条[18]に盛り込まれ、今後具体化するために『名古屋議定書の政府間委員会（ICNP)』が設置された。多国間利益配分の仕組みについては、すでに『食料農業植物遺伝資源条約(ITPGR－FA）』の中で利益配分メカニズムの一つとして規定され実施されている。このメカニズムを生物多様性条約にも適用し、出所がわからない遺伝資源についてこの多国間利益配分の仕組みを適用しようという考え方である。今後『名古屋議定書の政府間委員会』で議論されていくものと思われる。

資源国での生物多様性法の制定と運用状況

生物多様性条約に書かれている利益配分に関する条項は第十五条であり、そこでは、遺伝資源に関する資源国の主権的権利、遺伝資源の利用から生じる利益の公正かつ衡平な配分、遺伝資源を取得する際には、相手国から事前同意（PIC）の取得などが規定されている。この条文を読む限り、遺伝資源を資源国から自由な持ち出しは禁止されていると理解される。しかし、生物多様性条約の利益配分を実効ある具体的なものにするのは、各国の関連国内法にゆだねられていることを忘れてはならない。つまり、各国は条約の決まりを外れない限り、国内の経済事情と利益配分への要求に従って国内法を制定し、規則を定めて運用することができる。

各国が自国内の生物多様性法を制定するには困難であり、現に国内生物多様性法を定めている国はまだまだ少ない。生物多様性法は遺伝資源を巡る幅広い分野をカバーしているため、国内の政治・経済状況によって多くの利害関係者がある。例えば日本も国内法の制定の動きはあるが、遺伝資源を巡る各省の関係は複雑である。『カルタヘナ議定書[19]』に基づく日本の『カルタヘナ法』[20]によって、学術探索研究は文部科学省、農業作物、園芸関連は農林水産省、医薬品、健康食品あるいは化粧品関連は厚生労働省、その他の遺伝資源産業は経済産業省、環境保護については環境省がそれぞれ所轄している。更に、遺伝資源に関連する伝統的知識は知的財産を扱う特許

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18 第十条：地球規模の多国間利益配分の仕組み: 締約国は、遺伝資源及び遺伝資源に関連する伝統的知識が国境を越えて存在する場合、又は事前の情報に基づく同意の付与若しくは取得が不可能である場合に、その利用から生じる利益の公正かつ衡平な配分に対処するため、地球規膜の多国間利益配分の仕組みの必要性及び態様について検討する。この仕組みを通じて遺伝資源及び遺伝資源に関連する伝統的知識の利用者が配分する利益は、生物多様性の保全及びその構成要素の持続可能な利用を地球規模で支援するために用いる。

19 外務省；カルタヘナ議定書：生物の多様性に関する条約のバイオセーフティに関するカルタヘナ議定書：Cartagena Protocol on Biosafety、
http://www.mofa.go.jp/mofaj/gaiko/kankyo/jyoyaku/cartagena.html。

20 遺伝子組換え生物等の使用等の規制による生物の多様性の確保に関する法律：平成十五年六月十八日法律第九十七号；
http://law.e-gov.go.jp/cgi-bin/idxselect.cgi?IDX_OPT=5&H_NAME=&H_NAME_YOMI=%82%A0&H_NO_GENGO=H&H_NO_YEAR=&H_NO_TYPE=2&H_NO_NO=&H_FILE_NAME=H15HO097&H_RYAKU=1&H_CTG=1&H_YOMI_GUN=1&H_CTG_GUN=1。

庁の所轄かもしれないが、現行の知的財産関連法にそぐわない面が伝統的知識にはあり、むりやり知的財産関連法で規制することは困難である。政治の面ならず経済面あるいは一般の常識面からも、多くの問題がある。最近の環境保護運動は高まり、遺伝資源を巡る施策にも多くの意見が寄せられる。国内の少数民族の意向を無視することもできない。農業を始め多くの遺伝資源を扱う経済活動を阻害するようなこともできない。これらの各界からの意見を集約し、生物多様性条約の精神を基本とした国内法を制定することは至難のことであると考える。

いくつかの国で生物多様性条約に基づく国内法を制定している国があるので、それらを概観し、現状と課題を明らかにしたい。インドでは 2002 年にインド生物多様性法(Biodiversity Act)[21]が成立し、その運用を行なう組織として生物多様性局（National Biodiversity Authority : NBA）[22]が国、地方政府、自治体レベルで作られ、運用規則に基づいて活動している。インドの生物多様性法の詳しい内容は省略するが、特徴として、外国人等が参加している組織は NBA による事前の承認なしには生物多様性に関連する活動を行うことはできないという内外格差がある。また、インド原産またはインドから取得された生物資源に関する研究結果を、NBA の事前の承認なく上記の人や組織に移転することが禁じられる。したがって、学術研究で、研究サンプルを国外の共同研究機関に持ち出すことは厳禁であり、研究の停滞を招く。インドから得られた遺伝資源に関する発明について、インド内外での知的財産権を申請する者は、すべて NBA の事前の承認を得ることが要求される。このように遺伝資源探索をインドで行なうには、相当厳しい条件をクリヤーする必要がある。また、国内法が制定されて日が浅いこともあり、さまざまな利害関係により、運用が一致しない場合がある。その典型的な例がコモディティ例外の取り扱いである。インドでは国内の農業経済を重視して、農作物をコモディティと規定し、インド生物多様性法の例外として取り扱っている。しかし、コモディティの分類があいまいなため、運用が異なることがある。最近の例では、米国 Monsanto とその関連会社が、インド生物多様性法に基づき提訴される事件[23]がある。Monsanto のインド子会社 Maharashtra Hybrid Company (Mahyco) が、インド学術研究所と共同で、在来種なすびに Bt 遺伝子組換え実験を行うことになった。しかし、NBA が違法な遺伝資源へのアクセス、あるいは在来種はコモディティではないとして、Monsanto とその関連会社を生物多様性法違反で提訴した。Monsanto の遺伝子組換え技術はフリーで供与され、インド研究所の自由意思で実施することができる。あくまで学術研究であり商用目的はないと考えて、NBA への届出をしなかった。この点をインド生物多様性法違反とされたと思われる。また在来種なすびはコモディティではないとする見解も Monsanto 側の主張とは反する考え方である。この事件の背景は、インド政府あるいは農業界の Monsanto 遺伝子組み換え作物技術およびその遺伝子組換え種子が広まるのを懸念したことが、大きな動機であったことは容易に推測できる。

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[21] India;" THE BIOLOGICAL DIVERSITY ACT, 2002 No. 18 OF 2003", February 5, 2003, http://www.genecampaign.org/home/Biological%20Diversity%20Act%202002.pdf。

[22] National Biodiversity Authority:NBA と略; http://nbaindia.org/。

[23] Lucas Laursen; "Monsanto to face biopiracy charges in India", *Nature Biotechnology*, **30**, 11, (2012), oi:10.1038/nbt0112-11。

ブラジルの正式な生物多様性法はないが、現在運用されているのに『遺伝財産，関連する伝統的知識および技術移転に関する暫定措置条例（暫定措置条例 No. 2.186-16/1 号）』[24]がある。正式の生物多様性法の法案として『ブラジル生物多様性法案 DF, CEP 70.150-900』[25]が検討されている。暫定措置条例 No. 2.186-16/1 号の特徴は、利益配分として、契約当事者間で公正かつ衡平な利益配分がされるが，連邦政府が当事者でない場合でも，連邦政府に確実な利益配分がなされなければならないとされている。その利益配分の構成要件には、利益配分の定義，ロイヤリティの支払い，技術へのアクセスと移転，製品あるいはサービスの無制限ライセンス，人的資源の訓練・研修等がある。本暫定措置令に従わなかった場合，製品あるいはサービスが知的財産によって保護されているかいなかかにかかわらず，その販売総額あるいはライセンス契約収入の20%相当の賠償金を支払わなければならない。一方の契約当事者は，公共地あるいは私有地所持者，原住民社会あるいは原住民組織の代表者であり，他方はアクセスが認められたブラジル国内機関である。外国からの直接アクセスは認められないと内外格差を設けている。特許出願には出所開示義務がある。特許権の付与は，本暫定条例と規則の遵守を条件とし，違反する場合は認められない。また，遺伝資源に関連する伝統的知識の出所を特定することも必要である。

このようにブラジルの生物多様性関連法は、ブラジル国外からアクセスするに、非常に厳しい条件を設定しているといえる。特に、ブラジルのアマゾンで行なわれる学術探索研究に非常に厳しい目で監視している。そのため、ブラジルは生物の多様性に最も富んだ国であるにも関わらず、生物の分類すら進んでいない学術研究が停滞した状況にある。アマゾンで採取した新種の植物の遺伝子解析をしようとしたブラジルの研究機関が、植物サンプルを欧州の共同研究機関に送ろうとしたが、当局によって差し止めになった事例もある。象徴的な事件は Marc van Roosmalen の逮捕である [26]。Roosmalen はアマゾンの霊長類研究者であり、20 年間アマゾンで研究し、7 種の新種のサルを発見した。しかし、当局はブラジル生物多様性関連法の違反で Roosmalen 逮捕し監禁した。その後、国際的な学会等の圧力運動により釈放された。その時 Roosmalen が受けた判決は、許可なく動物保持、飼育、窃盗した罪であり、刑罰は 15 年 9 ヶ月の拘禁刑、約 8 万ドルの罰金であった。しかし、この事件の背景には森林開発業者の圧力があったとうわさされている。開発計画中の森林に新種の霊長類が見つかると、その森林開発が延期あるいは中止しなければならなくなることを恐れたためである。このように、利害関係が相反すると、力の強い開

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[24] BRAZIL ; “PROVISIONAL MEASURE No. 2.186-16 OF AUGUST 23, 2001”, http://www.grain.org/brl/?docid=850&lawid=1768。

[25] BRAZIL; “Brazilian Draft Bill of Law Covering the Collection of Biological Material, Remittance and Transport of Biological Material, Access to and Protection of the Associated Traditional Knowledge and Rights of Farmers and the Sharing of Benefits DF, CEP 70.150-900”, http://www.uslaw.com/library/Patent_Law/Brazilian_Government_Published_Bill_BioprospectingBiopiracy.php?item=52931。

[26] Evan Ratliff; “Why Does This Prominent Amazon Researcher Face 14 Years in Prison for Biopiracy?”, WIRED MAGAZINE: 16.06, May 19 2008, http://www.wired.com/science/planetearth/magazine/16-06/mf_monkeybusiness?currentPage=all。

発側が弱い探索側を押さえつける例として Roosmalen 事件は象徴的であると考えられ、開発と研究の調和が必要なことを示唆している。

遺伝資源の実際の産業利用状況とそこから見える課題

このような生物多様性条約を巡る政治的な南北対立にもかかわらず、日本の産業界では、古くから遺伝資源の利用探索研究が続いている。微生物や植物から有用な医薬品を見出した医薬品業界では成果を上げている。土壌から単離した微生物の培養物から抗生物質や抗がん剤を見出す研究が 60 年代から日本の製薬業界で盛んに行なわれている。この微生物探索は、いまでもいくつかの日本の医薬品会社は継続しており、日本のみならず海外にまでサンプルとなる土壌等を求めて活動を拡大している。また、海外の農産物を利用することは古くから行われており、多くの外来品種が存在する。現在では、多くの農業用作物を改良するために海外から野生種等の遺伝資源を導入し、新品種の開発に用いることも盛んである。資源国の伝統的知識に基づく健康食品素材を探索する研究活動も盛んである。

しかし、産業によって経済的事情が異なるため、遺伝資源の利用の仕方や利益配分の考え方はそれぞれ異なるのが実情である。それをまとめたのが図 1 となる。

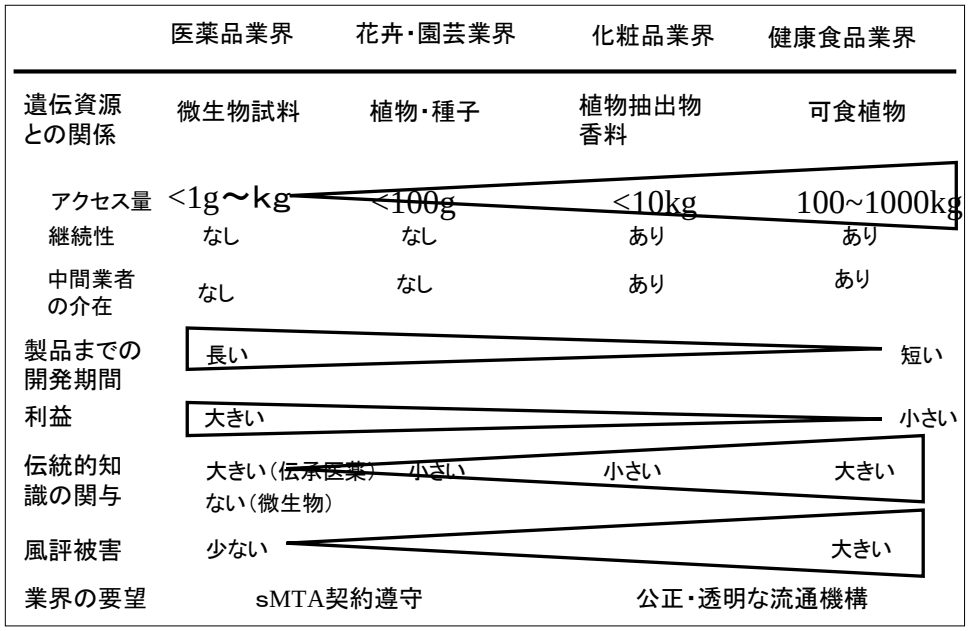

図 2　産業セクター別遺伝資源利用ビジネスの実情

重要な点は、遺伝資源にアクセスする量が大きく異なる点であり、大量に継続的に必要とする化粧品素材や健康食品素材の分野が遺伝資源の利用産業としては一番大きいといえる。その中でも、健康食品素材の分野では伝統的知識と深く結びついており、また資源国内での流通、消費と

重なる場合があり、輸出によって資源国内での供給が少なくなり、価格高騰する問題は資源国内での風評に発展しやすい。本図から明らかなように、産業分野によって利用形態あるいは利益が異なるので、問題の所在も当然異なる。共通していえるのは、社会的責任は厳守し、資源国の法律は遵守することである。伝統的知識の関与は、微生物探索を行なう医薬品業界では全くないが、可食物を扱う食品・健康食品業界では決定的な意味を持つことを強調しておきたい。つまり、伝統的知識の取り扱いをWIN-WINの精神で行なうことが健康食品関連業界の成功のキーとなる。

このように産業によって遺伝資源の利用形態が異なるので、利益配分に対する産業界の考え方、問題意識もさまざまである。医薬品会社は、ライセンスという制度にはなじみがあるため、遺伝資源利用に対する利益配分もライセンスにおけるロイヤリティを支払うのと同様の感覚を持っており、利益配分に大きな違和感はない。いままで、医薬用微生物探索を批判した資源国内での運動は見られない。微生物は一度採取、分離されると、資源国とは関係のないところで研究開発・販売が進むからである。しかし、資源国では、医薬品は高収益企業とみなされているので、利益配分への期待は高く、それが裏切られたときの失望感は高い。

一方、化粧品素材や健康食品素材の産業分野にはいくつかの特殊性があり、合理的な契約の形成が困難である。化粧品素材、農産物、健康食品素材は、その原料である遺伝資源を資源国から金銭的決済で購入しているため、利用企業からすればすでに利益配分は済んでいるとの感覚を持っている。資源国の権利を認めたとしても、すでに消尽しているとの考え方もある。更に複雑なのは、資源国からの遺伝資源輸入経路は、多種多様であり何段階にも渡って受け渡されているため、最終的な利用企業は資源国のアクセスポイントを全く知らないという状況が生まれる。そのため、利用企業が最終製品を作り販売し利益を得たとしても、どこにどれだけ利益配分をするのかわからないという状況になる。遺伝資源収集業者は多数の国にまたがって収集している可能性もあるし、そもそも収集業者はその収集先を教えることはない。つまり、事前の情報に基づく同意の取得が不可能な状況がビジネス形態として普通のことである。資源国関係者が、食品や化粧品分野が利益配分について一般的にローリスク/ローリターンであることを理解していないことも悩ましい問題である。医薬品なみの利益配分を要求されても、食品や化粧品分野業界の常識を越え、ビジネス的に不可能であることは、なかなか資源国に理解してもらえない。資源国内での農産物供給とのバランスも考慮しなければならない。資源国では生産システムが不備な遺伝資源を急に利用国で大量に利用されると、資源国での遺伝資源の乱獲が起こり、枯渇のみならず食料危機・経済危機へ発展しかねない。つまり、利用国で利用するには資源国の生産システムの構築が必須となる。生産システムの構築は、資源国に雇用促進を及ぼすので、一種の非金銭的利益配分ということができる。

資源国等のネガティブキャンペーンのターゲットになりやすいのは、生活関連品を製造販売する食品業界である。これは資源国との関係が深く、遺伝資源の利用国での利用状況が資源国の農業経済に大きく影響するからである。資源国でも製品販売を行なっている企業があると、ネガティブキャンペーンが風評被害を生み、資源国での不買運動につながるという危険性を秘めている。したがって、これを防止するには、利用企業の社会的責任における遵法精神と資源国でのさまざ

まな活動が必要となってくる。

健康食品や化粧品の会社は、生物多様性条約のアクセスと利益配分について、資源国の規制は今後ますます強化されるだろうと考えている。しかし、これらの業界の現状は厳しい。小規模な健康食品会社は遺伝資源探索までの余裕がないうえ、アクセスと利益配分の法規制に対応できる社内人材を持っていない。中程度の規模を持つ健康食品関連会社の中には、新しい遺伝資源探索に意欲的なところもあるが、アクセスと利益配分に関する契約には経験がなく、探索を躊躇せざるを得ないのが現状である。これらの現状の問題を打開すれば、積極的な遺伝資源探索事業は可能となり、生物多様性条約の第二の目的である持続的な利用が達成できるものと考える。

産業利用における遺伝資源アクセスと利益配分の考え方

健康食品や化粧品の素材を扱う中小企業は、資源国との相互理解と信頼に基づき、国際的取決めに従って、アクセスと利益配分解決を行なうべきである。そのための方法として、解決に経験のある専門家集団を組織するのが効率的であると主張したい。アクセスと利益配分について、遺伝資源へのアクセスなくして利益配分はないという視点と、生物多様性条約のアクセスと利益配分問題は当事者がWIN-WINの精神を持って誠実に交渉するという視点が必要であると考える。至極当然のようにみえるが、これらを実践することは相当な努力を要する。なるべく自社に有利なような考え方で望めば、合意に達することは困難であろう。

利益に関する詳細なデータは利用者側にしかなく、資源国は一方的に知らされるだけでそれを確認するすべはない。したがって、利用者に対する信頼感が醸成されていないと、利益配分を公正かつ衡平に行なうことは困難になる。利益配分の考え方は、利用側のビジネス事情により異なることを資源国によく説明し、理解をしてもらうことが信頼感を獲得する最も重要な活動である。医薬品なみの利益配分を健康食品に求められても不可能であることを理解してもらわなければならない。

実際の遺伝資源アクセス契約にみる利益配分の事例

遺伝資源を利用するビジネス形態、特に原料である遺伝資源との関連で分類し、利益配分のあり方について考察する。ここでは、遺伝資源の国境間の移動の形態によって三つに分類する。第一のビジネスタイプは、遺伝資源の定常的な移動を伴わない産業である。一旦遺伝資源標本が得られれば、永続的な資源国との関わりがない。これには、微生物から医薬品化合物の探索や花卉・種苗が主な産業である。両業種は開発期間や利益率に大きな差があるが、遺伝資源は定常的に移動を伴わないので、利益配分についてアクセス許可料的性格の一時金と売上利益に対するロイヤリティを基本とする契約形態で対応できる。第二のビジネスタイプは、遺伝資源の定常的移動を伴う産業で、主に食品・健康食品素材、化粧品素材、漢方生薬などが主な産業である。これらの業界では、第一のビジネスタイプで行なわれるライセンス形式の利益配分契約では不備である。

なぜなら、これらの業界では、原料の購入は金銭取引で決済済みであり、利用者側は利益配分の二重払いはできないと考えているからである。もう一つの大きな理由は、遺伝資源を安定して国境移動させるには、自然界からの採取では限界であり、人為的な生産体制の確立が将来的に必要であるからである。したがって、定常的な国境移動を伴う業界においては、ライセンス形式と異なるより複雑な利益配分システムを組み込んだ新しい契約が必要とる。第三番目はビジネスではなく学術探索研究の場合である。学術探索研究で利益配分を考慮することは困難である。利用国の学術研究者は、商売より論文発表が第一と考え、ビジネス計画は通常持っていない。しかし、学術研究成果として特許が得られた場合あるいはバイオベンチャーを設立した場合などは、ビジネスに直結し、特許権のライセンスによって直ちに利益がでる可能性があることを契約に入れる必要があるだろう。資源国では学術研究を商用研究と区別して考えることは通常行なわない。むしろ学術研究の成果が、商用研究と同様の利益が出ていると考えることが多い。

ここで、実際にどのような契約が行われ、利益配分が合意されているか、いくつかの典型的な事例を紹介する。第一のビジネスタイプである医薬・健康食品関連で行なわれたロイヤリティ形式の利益配分の例として、南アフリカの Hoodia が典型的な契約を行った[27]のがよく研究されている。サボテン Hoodia gordonia を食すると食欲が減退するというのが、南アフリカ共和国の砂漠地帯の原住民 San 族の伝統的知識であった。この Hoodia の活性成分を追究する研究が、南アフリカ共和国研究機関 Council for Scientific and Industrial Research（CSIR と略）で行なわれ、有効成分を発見した。CSIR は Hoodia の有効成分に関する特許をとり、特許ライセンスにより一時金を得ている。その後ライセンス先が開発を断念したため、他社に再ライセンスし、健康食品として現在開発中と報告されている。本 Hoodia を巡る問題は、CSIR と原住民 San 族の間での利益配分である。さまざまな議論が行なわれ、CSIR は原住民団体である SA San Council と MOU を締結し、利益配分契約を締結した。利益配分契約の特徴は、利益配分を San 族の個人に直接するのではなく、San 族が組織した信託組織に配分することになっていることである。資源国内での利益配分の仕組みを信託組織という形態を構築したことは、今後の資源国内での利益配分に参考になる。San 族は南アフリカ共和国のみならず周辺のボツワナ、ナミビア、アンゴラにも分布しているが、それらの国に住む San 族にも金銭的利益配分の恩恵を受ける権利を与えたことは、伝統的知識の利益配分の考え方として画期的であるといえる。

食品関連では稀であるが、ロイヤリティ形式の利益配分を行なった例として、エチオピアの Teff 契約がある。エチオピアの主要な伝統的穀物である Teff にアクセスするため、オランダの健康食品会社はエチオピア政府系団体（IBC と略）と 10 年間のアクセスと利益配分契約を締結した。契約内容によると、利益配分として一時金を 2007 年＋2008 年＋2009 年の総純利益の平均の 1％と決め、すでに 430 万ユーロを支払っている。ロイヤリティは、オランダの会社が開発した Teff 新品種の種子を売った場合、その利益の 30%となる。更に Teff 関連製品の正味利益の 5%（最低利益配分として 2 万ユーロ/年）を Teff の保護のための基金に寄付することになってい

[27] 森岡　一;『アフリカ諸国の開示した契約にみる植物遺伝資源へのアクセスと利益配分の考え方』、*AIPPI* **53 (11)**, 705-714、2008。

る。食品業界としては異例のライセンス契約を行った理由は、契約によりエチオピアの Teff へのアクセス権の独占を狙ったためである。実際の契約では、エチオピアの Teff はすべてオランダの会社に独占的供給することになっており、他の会社が同じような製品を作るためにエチオピアの Teff にアクセスしてもエチオピア政府は許可しないことになっている。Teff のアクセスと利益配分契約は問題であると考える。公共性の強い遺伝資源に独占権を与えることは、心情的に疑問を感じる。実務的には、利用国の一企業に独占権を与えた場合、その遺伝資源の運命は、その一企業の経済的事情に強く影響される。成功し市場にでれば両者とも満足であるが、失敗した場合全くなにも資源国には利益配分は入らないという危険性がある。

第二のビジネスタイプである遺伝資源の定常的移動を伴う産業では、原料購入に伴う利益配分を行なっているとの認識が強いという点と永続的に資源国と原料の安定的供給が必要という特徴がある。実際の産業では、天然香料成分を野生あるいは栽培の植物抽出物に求める化粧品素材分野と、農産物＋伝統的知識が必須である健康食品素材分野がある。この業界で利益配分を実施するのにライセンス形式だけではうまく機能しないと思われ、新たな配分メカニズムの考案が必要である。アクセスと利益配分契約を困難にしているのに二つの原因が考えられる。すなわち、利用者が遺伝資源はアクセス時点で原料購入として金銭決済しており、ロイヤリティを払う感覚がないことである。もう一つは、原料流通経路が複雑で、誰が誰に利益配分するか決定することが困難である点である。化粧品素材あるいは健康食品素材の入手経路をまとめたのが図２である。複雑で多数の入手経路があるため、それぞれで利益配分を考慮した契約を結んだとしても、実効性は低いと思われる。アクセスと利益配分を適切に行なうためには、これらの複雑で多数の入手経路を包括した組織体が必要ではないかと考える。

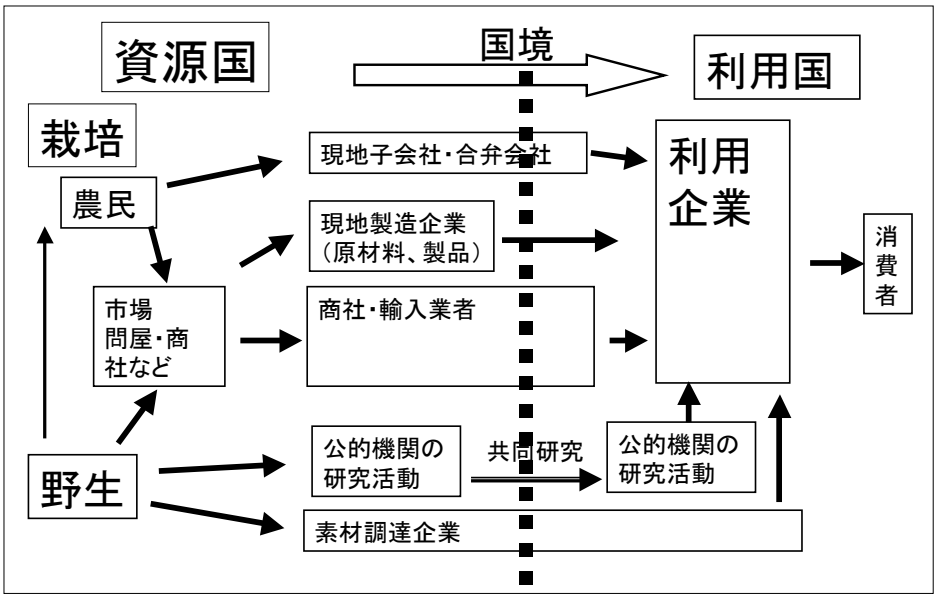

図 3　化粧品素材・健康食品素材の入手経路

実際、化粧品素材業界の中で、新しいアクセスと利益配分の仕組みを作ろうという運動が起こっている。フランスの化粧品素材取引業者である Aldivia は、アフリカの遺伝資源供給組織である PhytoTrade Africa などとともに Union for Ethical BioTrade（UEBT)を組織した[28]。本団体の目的は、生物多様性条約を尊重した遺伝資源の貿易、商取引を推進し、消費者へのプロモーション活動を行なうことである。重要な活動は、メンバー企業の持続可能な遺伝資源の利用促進と資源国の経済的発展を援助することに向けられている。

一部の農業用遺伝資源の取引は、生物多様性条約と異なる食料農業植物遺伝資源国際条約（ITPGR-FA）によって規制されている。ITPGR-FA とは、ジーンバンク等の遺伝資源保有機関が保有する特定作物３５種へのアクセスに関する条約である。植物園等の保存植物を利用する種苗・花卉業界では受け入れやすい制度であるといえる。農業用遺伝資源を利用する健康食品・食品業界でも、自社で農業用遺伝資源を栽培し利用する場合に利用できる。ITPGR-FA では既に利益配分システムとして、多国間利益配分であるマルチラテラルシステム（MLS）という制度が実行されている。MLS の特徴は、一国の主権的権利を越えた制度で、利益配分を国際連合食糧農業機関の特定組織にプールすることである。そこから公共性の高い事業の資金として分配されている。そのために、農業用遺伝資源の利用者は標準試料移転同意書（sMTA）を結ぶ必要がある。農業用遺伝資源関連品が販売された場合、売上から 30%引いた額の 1.1%を利益配分することになっている。日本は ITPGR-FA に加盟していないので、日本の保有する農業用遺伝資源についてこの MLS を用いることはできない。

このように第二のビジネスモデルでは第一のモデルより複雑になっており、単なるライセンス契約だけでは利益配分問題は解決しない。さらに、遺伝資源に関連する伝統的知識問題も解決する必要があるし、素材原料供給問題も相互契約の中に盛り込まなければならない。資源国と利用者の両者が参加する共同の第三者組織を形成し、その中で諸問題を解決していくメカニズムが現実的であると考える。化粧品素材業界で行なわれている Union for Ethical BioTrade や食品業界で広まっている Fairtrade[29]などが今後の方向性を示していると思う。

学術研究における利益配分

第三番目は学術探索研究の場合である。学術研究の目的として、資源国の遺伝資源探索研究を行っている学術研究者は多い。特に新規な化合物を単離同定し、その作用を調べる薬学的研究や農学的研究は多数論文として発表されている。資源国の伝統的知識を基に、甘味物質を多数発見した栗原らの研究[30]は有名である。

学術探索研究の最終目的は新発見とその結果の論文発表であり、産業化の意識は低い。そのた

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[28] 森岡　一;『化粧品業界の生物遺伝資源利用とその課題』、*バイオインダストリー*、**26(9)**、64-71、2009。

[29] 森岡　一；『農産物の認証制度とその利益配分の考え方 Fairtrade labeling コーヒーを中心に』、*知財ぷりずむ*、**6(68)**、16-26 、2008/5。

[30] 栗原 堅三 ；『味と香りの話』、B004L1G3CS 岩波新書、1998。

め、研究者単独あるいは大学が、資源国とアクセスと利益配分のための契約をする際は、あまり真剣に利益配分について考慮することは少ないと推測する。しかし、現実には大学には産学連携本部も設置され、特許出願や産業への応用を考えている。これは、特許権のライセンスによる収入を期待しているからである。この入口と出口のギャップを埋める努力をしない限り、問題解決にはならない。一方、当事者の共同研究相手である資源国は、学術研究であっても利益配分に関しては産業用と区別することは少なく、学術研究に利益配分を要求することが多い。その結果、利益配分は相当安直に決められている傾向が強いと思われる。慎重に契約交渉をする場合は、利益配分の項目の議論を先送りして、アクセス段階では明確にしない場合がある。

大学等の遺伝資源探索研究の中で結ばれた契約[31]で、利益配分の詳細を含めた例を紹介する。カリフォルニア大バークレー校は、サモアの伝統的知識を利用して、サモアに生育している Mamala (*Homalanthus nutans*) という植物から、抗 AIDS 物質 Prostratin を発見した。この新規化合物の取り扱いについて、カリフォルニア大バークレー校とサモアの間で、この抗 AIDS 化合物とそれを生産する遺伝子に関するアクセスと利益配分契約を締結している[32]。それによると、カリフォルニア大バークレー校が得た金銭的利益は、カリフォルニア大とサモアで 50%：50%に配分することになっている。サモアに分配された利益配分は、更にサモア国内の関係者に分配されるのが特徴である。伝統的知識を保持する村に厚く分配されるだけでなく、その村の伝統的知識保持者である治療師の子孫にも分配される。このように末端の関係者、特に伝統的知識保持者の治療師の子孫まで利益配分を与えることは画期的な考え方であるし、伝統的知識と利益配分の良い例を示しているといえる。

学術探索研究におけるアクセスと利益配分契約問題を解決するには、学会を中心に原則あるいはガイドラインを作成し、日本国内だけでなく資源国にも周知徹底すれば、理解が得られやすいのではないかと考える。このような観点で作られたガイドラインの例として、米国国立衛生研究所（NIH）が作成した Letter of Collection（LOC）[33]が広く大学などで用いられている。LOC は、米国の研究機関が対癌撲滅政策[34]に基づく抗がん物質探索を行なうための遺伝資源探索用に作成された。LOC の特徴として、成果の商用利用への移転から 12 ヶ月以内に、NIH の技術移転部は資源国の機関と利益配分に関する契約を締結しなければならないとしている。更に、利益配分の対象は、直接生物遺伝資源から単離された化合物のみならず、誘導体、類縁体やリード化合物、さらにはそれらの合成方法などにまで及ぶとされている。また、資源国の研究者を教育・訓練をすることが決まっており、また、NIH の中の研究所で行われる抗がん剤探索研究の一部に、資源国の研究者が 1 年間参加することも可能であるし、資源国が独自に探索研究を行うことも可能である。しかし、抗がん剤等の医薬品を念頭に置いた契約であるので、食品や化粧品で

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31 Robert Sanders; “Landmark agreement between Samoa and UC Berkeley could help search for AIDS cure”, 29 September 2004, http://berkeley.edu/news/media/releases/2004/09/29_samoa.shtml。
32 Robert Sanders; “Landmark agreement between Samoa and UC Berkeley could help search for AIDS cure”, 29 September 2004, http://berkeley.edu/news/media/releases/2004/09/29_samoa.shtml。
33 National Institutes of Health; ”Letter of Collection（LOC）”, http://ttc.nci.nih.gov/forms/loc.doc。
34 Richard Nixon; “Annual Message to the Congress on the State of the Union.”, January 22, 1971, http://www.presidency.ucsb.edu/ws/index.php?pid=3110#axzz1zozqxS9n。

は使えない。また、単なる遺伝資源の探索収集し分類研究のような博物学的研究は、全く利益配分に結びつかないので、植物園[35]や学会[36]の原則のほうが参考になると思われる。

資源国内での関係者間の利益分配の考え方

アクセスと利益配分は資源国の政府機関と利用国の私企業の間で結ばれる場合が多い。これは、利用者が、できるだけ権威のある上位機関と契約したほうが後の紛争のために有利になると考えることが理由のひとつである。したがって、資源国の利益配分の受け取り窓口は、契約先である資源国の政府機関になるのは自然の成り行きである。政府機関が得られた利益を直接末端の関係者に分配することは考えにくく、おそらく、一旦政府の収入となり、公共事業等に使われるのが一般的ではないかと考える。南アフリカの Hoodia の例では、南アフリカの CSIR という国立研究機関がライセンス先からライセンス料をもらっていたが、San 族に分配しなかったため問題が発生している。このような PIC/MAT の契約形態では、資源国内の直接関係者が利益配分を直接受けたという実感はなく、いつも不満に満ちている。

利用者から得た利益配分を、どのようなメカニズムを作って関係者の間で分配していくのか、資源国内では重要な問題であると考える。この問題を解決しない限り、資源国内の直接関係者に不満が消えることはない。利用者にとっても、資源国内での利益配分を巡る紛争は、常に自身に跳ね返る危険性があり、他人事のように振舞うことは好ましくない。Hoodia の例を考慮して、南アフリカでは、生物多様性法の中で利益配分契約あるいは物質移転契約から得られるすべての金銭は、バイオ探索信託基金[37]という信託組織に支払われ、そこから直接関係者に分配するというメカニズムを法制化している。バイオ探索信託基金に支払われたすべての金銭は公共財産管理法の範囲に入る。信託基金の長官は、公共財産管理法に従い基金を管理しなければならないし、法に従って基金に責任を負わなければならない。バイオ探索信託基金は、金銭的利益配分と非金銭的利益配分の仕組みの組み合わせによる運営がなされている。食品業界でも、民間の取組みであるが、Fairtrade のように製品価格の中に直接生産者に支払うメカニズムが構築されている。いわゆるプレミアム価格、加算奨励金あるいは報奨金という制度である。最低価格から分離した特別な価格であり、生産組織、そのメンバー、生産地域の環境保護、福祉活動、社会改善などに投資するために作られた上乗せ価格ということができる。生産者に生産協同組合がある場合、プ

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35 Royal Botanic Gardens, Kew; Standard institutional ABS policies and agreements, www.kew.org/conservation。

36 Swiss Academy of Science; “Agreement on Access and Benefit Sharing for Non-Commercial Research”, http://www.bfn.de/fileadmin/ABS/documents/6C33Ed01__2_.pdf.。

37 南アフリカ共和国生物多様性法第 85 条：バイオ探索信託基金の設立；
第一項：利益配分契約あるいは物質移転契約から得られるすべての金銭はバイオ探索信託基金に支払われ、そこから利益関係者に分配されるべきである。
第二項：バイオ探索信託基金に支払われたすべての金銭は公共財産管理法の範囲 section 13(l)(f)(ii)に入るものとみなされる。
第三項：信託基金の長官は　(a)　規定に従い基金を管理しなければならない　(b)　公共財産管理法に従って基金に責任を負わなければならない。

レミアム価格全体が生産者組合の銀行口座に振り込まれ、その使途については組合員により民主的に決定される。実際は、生産者組合が地域社会の健康、教育、飲料水施設などの改良、市場知識の教育、ビジネス方法の改良、自然環境の保護などを自主的に行なう資金となる。

資源国内での公正で衡平な利益配分の適切な実施を行い、すべての直接関係者に利益を受け取った実感を持ってもらうメカニズムを構築するために、利用者も、利益配分を決める契約時にその配分の方法について注文をつけるべきである。特に、持続的生産と安定的供給システムを必要とする化粧品素材や健康食品素材業界では、資源国への継続的な支援が必要であるので、上記のようなメカニズムを提案すべきであると考える。すでに、私企業において、環境問題に取り組むため自主的に農業組織を援助する取組みが企業の環境レポート等で散見されるが、すでにこのようなメカニズムを運営しているならば、それを更に発展させるような取組みにすればよいのではないかと考える。

アクセス許可付き遺伝資源利用促進に向けた日本企業への提案

日本の遺伝資源利用企業の中には、それぞれ独自に資源国と交渉し、遺伝資源アクセス権を得て、独自の探索研究と開発を行っている会社がある。資源国のアクセス窓口は、経験豊富な政府機関一つであるが、利用企業は、それぞれ個別に交渉に臨まなければならない。政府機関と私企業の間では、なかなか交渉を対等に行うことが難しい上、資源国側の都合で交渉が長引くのが常である。また、その契約内容は企業秘密として公開し共有されることはない。利用企業がアクセス許可を得た遺伝資源のうち、製品まで開発され利益を生むのはおそらくごくわずかであり、残りの大部分は探索済みでデータはあるが、未利用状態になる。未利用では利益を生むことはない。しかし、アクセス権を得ている企業が、他企業に未利用資源を譲り渡すことは、競争の観点から困難であると考えられる。

したがって、未利用のアクセス許可付き遺伝資源とその探索データの利用をいかに促進するかは重要な課題となる。そこで、アクセス許可付き遺伝資源を共同で利用できる組織を構築することを提案する。このような本前競争的共同体モデルの概略は下記の図 3 に示した。

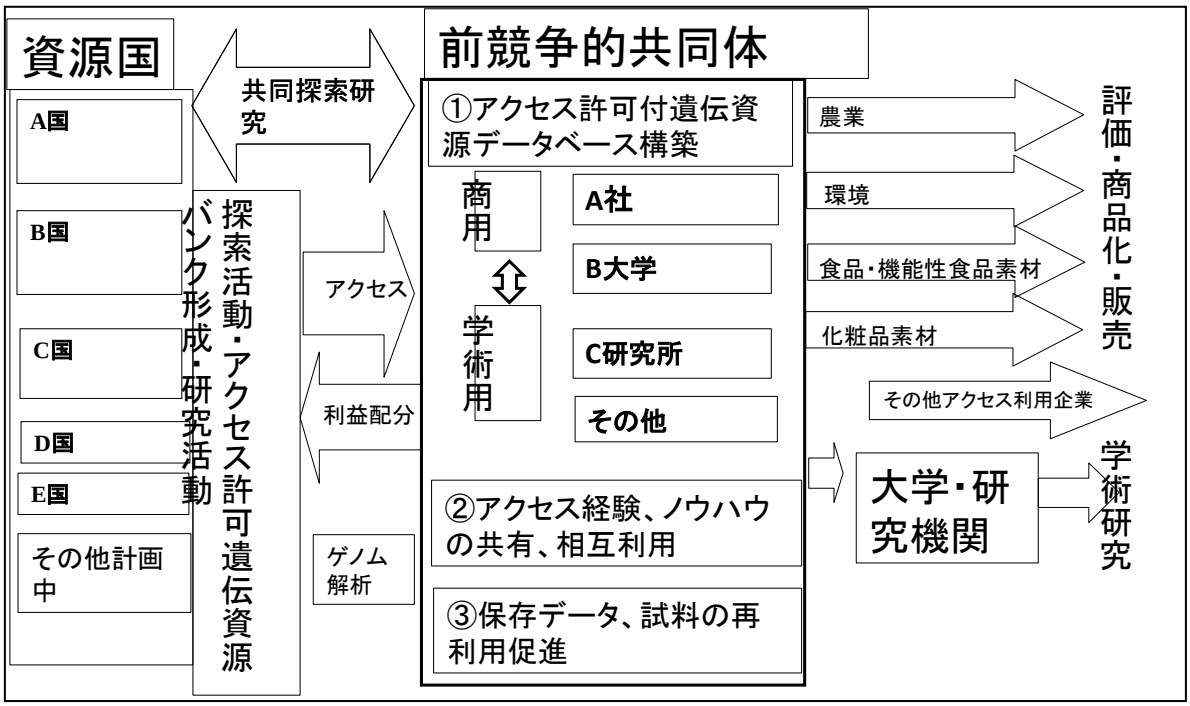

図 4　アクセス許可付き遺伝資源利用促進モデル（案）

個々の組織が持つアクセス許可付き遺伝資源と探索データの統合化、相互利用を促進するのが骨子である。更に、共同体を作ることにより、個々の組織が秘密にしていたアクセス契約経験やノウハウ、資源国との紛争解決経験などの共有化を図ることができるし、共同で解決に参加することも可能になる。そうすれば、経験を積んだ資源国窓口と対等に交渉を行なうことが可能となる。大学等が共同体に参加すれば、その遺伝資源アクセス権を利用することができるだけでなく、大学等は資源国への学術援助が可能となり、大学の国際共同研究も拡大させることが可能になる。

遺伝資源利用共同体モデルのスキームは、組合またはコンソーシアム形式の前競争的な民間推進組織である。特徴は、民間が主体的に資源国と行う。参加会社の利益確保を最優先とするため、優先的アクセス権を設定する。更に、共同体を作ることによって、資源国とのアクセスと利益配分の交渉が、利用国当事者の経験や能力が強化され、今まで以上に容易になる。共同体が資源国との交渉、管理業務を実施することができるようになれば、対資源国への窓口は一つに統一できる。いつも同じ担当者が資源国の同じ窓口担当者と交渉するので、相互の信頼性が高まる効果がある。交渉、紛争の情報交換が安易になり、経験を共有しやすくなる。ただし、国の支援がないので、運営資金不足と交渉が難航する可能性はある。公共性を保つために、公共資金で運営することが必要であるが、まず政府関係者の理解を得なければならない。将来的には、機能性食品等に関連した伝統的知識問題を交渉することも可能になるだろう。

このような前競争的共同体の探索対象は、機能性食品、化粧品素材、花卉・園芸分野に限定し、医薬品関連は除きたい。その理由は、既に医薬品関連の遺伝資源探索ではライセンス形式が運用されているからである。更に、機能性食品、化粧品素材、花卉・園芸分野では、開発コストが低

く、成果を比較的短期間で創出することが可能であり、利益配分が短期で達成できる。このことはすでにいくつかのシステムで証明されており、実績がでている。分野別優先権による独占性を確保することが可能なので、利用企業の独占性を満足させることもできる。当面は 3 年程度のアクセス優先権を考えている。その間は、成果の権利は共有だが、実施権は原則として利用開発者に帰属する。事業が発展すれば、このような前競争的共同体には、遺伝資源バンク/データベースという財産が残ることになり、遺伝資源バンク/データベースを用いて新たな利用企業にまで拡大することができる。また、契約ノウハウ、資源国とのつながりなどの無形の財産も残る。このような前競争的共同体を構築することによって、日本の遺伝資源のアクセスと利益配分を促進し、日本のバイオ産業を活性化することが可能であると信じる。

おわりに

生物多様性条約を巡る諸問題を解決するには、今後も多くの努力と長い年月が必要である。解決に向けた基本姿勢は、各レベルの当事者間の WIN-WIN に基づく相互信頼関係の醸成であると考える。解決に向けたアプローチとして、政治的取組みと企業レベルの実務的な取組みがある。両方とも非常に重要な方法で、片方に偏ることがあってはならない。つまり、民間の取り組みを無視して、政府間だけで妥協することは避けるべきである。

条約という性格上あるいは資源国の主権的権利を巡る問題であるため、政府間の交渉は重要である。政府間交渉には、複雑な状況を分析し最善の方法を探るべく、常に情報収集や分析研究を行うことが必要である。特に、遺伝資源の国際間移動に関する企業の実情について正確な情報を持つことが最も重要である。資源国内の地域の事情が異なり複雑であるため、資源国の中央政府だけを相手に交渉することは危険である。特に遺伝資源と関連する伝統的知識の利益配分を交渉する際には、地方の組織の方が有利である。

日本との交流に長い歴史を持ち、日本に対する理解のあるアジア地域を中心に取り組む地域戦略が求められる。交渉がまとまるか否かは、背景となる国情に依存するが、幸いにもアジア地域は日本と深い経済交流関係にあるため、交渉相手としてはふさわしいと考える。

実務的な遺伝資源へのアクセス交渉は、主たる課題である利益配分を実際に交渉しているため、現実に資源国が求めている本音についての情報や経験を持つことができる。しかし、この貴重な情報や経験を企業秘密というベールで覆ってしまうことは、利用国としての解決のチャンスを逃すことになる。貴重な情報や経験を持ちより、議論する場が強く求められている。このような場ができ、公共性が高まれば、当事者のみならず政府関係者は貴重な情報を得ることができるはずである。この共同体組織の中では秘密情報は公開されるが、この場から外に出ることはないので、一種の前競争的共同体ということができる。しかし、このような場を提案しても、それを実行するには運用資金問題など多くの課題を抱えており、一歩一歩進めるしか方法はないだろう。賛同者の参

以上