行政院國家科學委員會專題研究計畫　成果報告

國際規範有關遺傳資源之取得與利益分享機制之執行研究

(I)

計畫類別：個別型計畫
計畫編號：NSC94-2414-H-009-001-
執行期間：94 年 08 月 01 日至 95 年 07 月 31 日
執行單位：國立交通大學科技法律研究所

計畫主持人：倪貴榮

報告類型：精簡報告

處理方式：本計畫可公開查詢

中　華　民　國 95 年 10 月 27 日

行政院國家科學委員會補助專題研究計畫 ■ 成 果 報 告
□期中進度報告

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執行期間：　2005　年　8　月　1　日至　2006　年　7　月　31　日

計畫主持人：倪貴榮
共同主持人：
計畫參與人員：

成果報告類型(依經費核定清單規定繳交)：■精簡報告　□完整報告

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執行單位：國立交通大學科技法律研究所

中　華　民　國　95　年　10　月　25　日

（一） 計畫中文摘要

近十年來，對於生物遺傳資源的不公平、不合法利用，已為國際上欲積極解決的問題，尤其是先進國家對於遺傳資源豐富的國家（多為開發中國家）進行生物剽竊與生物探勘的情形層出不窮。為了防止生物剽竊並保護國家遺傳資源，在 1992 年通過的「生物多樣性公約（Convention of Biological Diversity，CBD）」，與 2001 年世界糧農組織的「糧食與農業植物遺傳資源國際條約（International Treaty on Plant Genetic Resources for Food and Agriculture，PGRFA）」，提出了資源取得與利益分享機制(Access to and Benefits-sharing, ABS)；個人在先前執行之國科會專題研究計畫包括 CBD 之研究(NSC 90-2420-H-009-003-)，與正執行關於糧食與農業植物遺傳資源國際條約之研究(NSC 93-2414-H-009-001-)中，已對 ABS 相關條文之法律涵義進行研究與分析，但是國際規範的宗旨與目標的達成，則有賴後續國際與國內法的執行。

此連續性計畫，為先前國科會補助的相關連計畫，擬對 ABS 機制後續的發展，與各國國內法的執行層面進行研究。研究重點將先著重分析 CBD 之 COP-6 於 2002 年提出之波昂準則（Bonn Guidelines）的後續執行與實踐；並檢視 PGRFA 關於 ABS 最新的活動與發展。進而執行各國國內實踐情形的比較與分析研究，本計畫主要之焦點為在遺傳資源法具領導地位的國家和地區，包括哥斯大黎加與安地斯聯盟等。為使本研究更具成效，即有必要對包括當地政府、相關公司、組織，及當地社群在內的關係人進行實際的田野調查。

各個國家實踐的層面與執行狀況將於本計畫中提出詳細的探討，期能分析比較各國家實踐情形的優缺點與立法背景，以提供我國在立法保護遺傳資源時的重要參考。
關鍵詞：遺傳資源、生物多樣性公約、糧食與農業植物遺傳資源國際條約、資源取得與利益分享、波昂準則

（二） 計畫英文摘要

During the past decade, the international community has sensed the serious inequitable and illegal consequence resulted from the bio-piracy and bio-prospecting activities of Western companies in genetic resources rich countries, mainly referring to developing countries. As a result, in order to safeguard the inherent interests of the countries under bio-piracy, a requirement on access to (resources) and benefits-sharing (ABS) has been initiated mainly by the 1992 Convention on Biological Diversity (CBD) and 2001 FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA). The previous projects supported by the NSC have been analyzing the basic legal implications of the provisions governing ABS mechanism. Nevertheless, the ABS device alone cannot satisfy the designed objectives and goal without a proper implementation in international area and national aspect as well.

The proposed continuing project following the prior projects aims to examine the current international and national implementation on ABS requirement. On the former, it is designed to explore the subsequent operation since the adoption of Bonn Guidelines in the COP-6 to CBD in 2002, which underlines the basic and more detailed framework in making the CBD mandates more feasible. The update activities of FAO's PGRFA will also be examined. A parallel work will focus on the analysis of national legislative and administrative measures in implementing the ABS. The priority will put two leading cases, Costa Rica and Andean practices, under scrutiny. To ensure the study of national practices to be more fruitful, tangible and effective, a field trip to those leading countries is essential, which will comprise an *in–situ* observation of the operation and interview with relevant stake-holders, including governmental officials, bio-tech. companies under the regulation and local communities.

By a comparative study of the implementation of ABS, the major contribution of the project is to assist the establishment of a proper legal framework for our country who currently is want of any official structure in regulating ABS based upon genetic resources under our jurisdiction.

Keywords: genetic resources, bio-piracy, CBD, PGRFA, access to and benefits-sharing, Bonn Guidelines

一、報告內容

(一) 前言

生物科技的發展使得自然界中各種資源的利用議題成為矚目的焦點，現代文明對於第三世界、第四世界生物資源豐富地區的「生物掠奪」其來已久，而相關文獻的記載與討論也甚豐富 (Kloppenburg, 1988 ; Juma, 1989)。如何使遺傳資源的利用更合理、有效，同時堅持對環境永續發展的承諾，已引起國際社會關注；各個國際組織均表達了積極的態度與立場，如：國際經貿組織（WTO）、聯合國（UN）、世界智慧財產權組織（WIPO）；同時已有多項重要的國際公約、條約、協定，與議定書直接規範遺傳資源之跨國活動，如：已生效數年的生物多樣性公約（Convention on Biological Diversity，簡稱 CBD），近期聯合國糧農組織(FAO)大會更於 2001 年 11 月通過的「糧食與農業植物遺傳資源國際條約」(International Treaty on Plant Genetic Resources for Food and Agriculture，簡稱 PGRFA)等。

CBD 提出的資源取得與利益分享（Access to and Benefit-sharing，簡稱 ABS）規範，從 1992 年通過以來即受到熱烈的討論，其後更為落實該公約的相關條文通過了波昂準則（The Bonn Guidelines）；準則包括適用範圍、遺傳資源提供國和使用國的責任與義務、遺傳資源獲取和事先知情同意程序(Prior Informed Consent, PIC)以及利益分享、IPRs 相關事項的雙方協定等原則，準則將指導和協助各國制定遺傳資源和利益分享的國家政策和法律，以及國家之間關於遺傳資源 ABS 協定的簽署和實施等。而各國如何在其國內法制的層面中予以落實，則為後續極為重要之研究議題。

個人在先前執行之國科會專題研究計畫包括 CBD 之研究(NSC 90-2420-H-009-003-)，與關於糧食與農業植物遺傳資源國際條約之研究(NSC 93-2414-H-009-001-)中，已對 ABS 相關條文之法律涵義進行研究與分析。惟僅討論各個公約、條約，與議定書之間個別的關係以及衝突與調和，以提供生物資源 ABS 機制在學理上與條文操作上的理論分析，應非足夠。

(二) 研究目的

本計畫研究重點將著重分析 CBD 之 COP-6 於 2002 年提出之波昂準則（Bonn Guidelines）的後續執行與實踐。此外，並從各主要國家的的實踐狀況來檢視國際規範揭示的原則與要求如何落實於國內法制的層面。

目前已有多個國家以及區域聯盟針對遺傳資源提出立法，如：安地斯山脈群落的會員國所正式通過取得基因資源的一般制度（Andean Community Common System on Access to Genetic Resources）、哥斯大黎加的生物多樣性法（The Costa Rican Biodiversity Law），以及非洲聯合科學、技術及研究委員會致力於相關部落權以及生物多樣性資源的取得之模範立法草案…等等，各個國家實踐的層面與執行狀況將於本計畫中提出詳細的探討，期能分析比較各國家實踐情形的優缺點與立法背景，以作為我國在維護遺傳資源利益及有效管理之立法的重要參考。

(三) 文獻探討

根據檢索，國內近期與遺傳資源相關的網站有台大農藝系郭華仁教授之網頁(http://seed.agron.ntu.edu.tw/IPR/)，該網頁收集育種家權利、生物多樣性以及植物品種保護相關資訊。又，國內有多位學者對於國際規範的內容，以及相互間的比較分析提出研究，唯仍欠缺國際規範實踐面的討論，而植物遺傳資源的維護與有效利用已是各國目前關注的重要議題，公約、條約所揭示的原則與目標與我國利益具密切之關聯性，因此雖然我國目前仍非為其中許多國際條約之締約國，但推動關於遺傳資源的立法仍為當前要務，此研究計畫分析各國實踐狀況對於我國的立法將提供重要的政策參考。

G. Dutfield 所著＜Intellectual Property Rights, Trade and Biodiversity＞係瞭解 CBD/ABS 制度之重要文獻，惟僅對遺傳資源法之國內實踐作簡單介紹，而欠缺深入之法制理論及利弊分析。

又各國制訂的制度、法案為本計畫重要的參考資料，唯檢視國外文獻資料多侷限於對其國內的法規如何與國際規範調和而提出立法建議，缺乏對於整合各國實踐優劣的討論研究，故本計畫不論對國內或是國外均將有重要的貢獻，可以整合國際規範後續在各國實踐

的狀況，同時提供國內立法的重要依據。

(四) 研究方法

1. 文獻蒐集分析

包括主要資料蒐集分析，如 CBD、FAO 相關文件、有關之國際條約以及各國國內相關法令等；及次要資料：如國內外期刊、網路資源和報導等。

2. 法律議題分析

運用歸納法、比較法、演繹法、與案例研究等方式進行分析。討論議題如下：

(1) 分析安地斯聯盟、秘魯、巴西、哥斯大黎加和美國等國家的政策、立法，以及行政規則如何落實國際規範的要求。

(2) 分析各國遺傳資源的特色，規範背景，以及其國內立法是否能回應該國的保護需求。

(3) 檢討上述各國立法狀況與各國際公約、條約規範的衝突與調和。

3. 進行必要之訪談

訪問植物資源學者，以充實本研究之專業背景；訪問政府主管機關，以明瞭國內法制現況計畫

4. 赴國外與包括當地政府、相關公司、組織，及當地社群在內的關係人，進行田野調查。

(五) 結果與討論

部分研究成果發表於《科技法學評論》，第二卷，第二期，頁 46-55 (2005)，民國 94 年 10 月 15 日出版。茲摘錄如下：

目前在 CBD 資料庫中收錄有 26 個國家實踐狀況，CBD 的報告將之分成三類：第一類係在生物多樣性或環境法律中提到 ABS 問題，但沒有制定細節，如阿根廷、古巴、剛比亞、肯亞、巴拿馬、烏干達等國。第二類為已經制定生物多樣性法律，且對於 ABS 有一般性規定之國家，如保加利亞、厄瓜多、墨西哥、尼加拉瓜。第三類則為對於 ABS 規定較為詳細的國家，如澳洲、玻利維亞、巴西、哥斯大黎加、圭亞那、印度、馬拉威、菲律賓、秘魯、南非、委內瑞拉等國[1]。

以下就對於 ABS 制度具有代表性國家之立法實踐為說明：

1 菲律賓

為管制遺傳資源的取得，菲律賓於 1995 年 5 月 18 日制定第 247 號行政命令[2]，環境與自然資源部並於 1996 年 6 月 21 日制定第 96-20 號部會行政命令[3]。

第 247 號行政命令為全球最早的取得遺傳資源法制，總計 15 個條文，其目的在於管制生物探勘。其將探勘活動區分商業及研究目的，須分別與主管機關簽訂學術研究協議書（Academic Research Agreement）及商業研究協議書（Commercial Research Agreement），並規定協議書之最低標準。申請者只有在踐行嚴格規定的 PIC 程序後才能與主管機關簽訂協議書，嗣後違反協議書時，主管機關得以片面終止協議。

第 96-20 號部會行政命令則總計 17 個條文，內容進一步詳細規定生物探勘之程序，包括基本政策、名詞定義、範圍、保護區內之生物探勘（Bioprospecting within Protected Areas）、申請生物探勘之要件與程序及簽訂協議書之程序等。

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[1] *See* CBD Doc., *Analysis of Existing National, Regional and International Legal Instruments Relating to Access and Benefit-Sharing and Experience Gained in Their Implementation, Including Identification of Gaps,* UNEP/CBD/WG-ABS/3/2 (Nov. 10, 2004), at 12-13.

[2] *Executive Order No.247: Proscribing Guidelines for the Prospecting of Biological and Genetic Resources, Their By-products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes, at* ＜http://www.grain.org/brl_files/philippines-bioprospecting-1995-en.pdf＞ (last visited May 17, 2005).

[3] *Department Administrative Order No.96-20: Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources, at* ＜http://www.grain.org/brl_files/philippines-bioprospectingeo247-1996-en.pdf＞(last visited May 17, 2005).

2 哥斯大黎加

為整合國家資源，在國內層面有效落實 CBD 之目標，哥斯大黎加於 1998 年 4 月 23 日通過了生物多樣性法[4]（Ley de Biodiversidad; Biodiversity Law），並於同年 5 月 6 日正式成為哥斯大黎加第 7788 號法律。

關於遺傳資源之取得，該法授權主管機關，制訂了「取得生物多樣性遺傳及生化資源之一般規則」[5]，進一步對申請許可之流程詳加規範。依據該法及上述規則之規定，欲於該國境內從事生物探勘者必須向主管機關轄下之技術辦公室（Technical Office）申請許可（access permit），並依照其目的之不同分為基本研究、生物探勘與商業開採等三類，除皆應取得探勘地點之保育區主管及土地所有人或原住民社群之 PIC 外，若為即五年內探勘次數達六次以上之持續性商業開採，尚須得到主管機關之特許（concession）後方能為之。

在利益分享方面，申請人應將相當於其所獲之權利金最高達 50%之金額（商業開採之情形），或其研究預算最高達 10%之金額（基本研究或生物探勘之情形），支付給同意探勘活動之當地社群或私人擁有者及哥斯大黎加的國家保育區系統（National System of Conservation Areas）。

3 巴西

巴西在州層次先行制定相關法令，如 Acur 及 Amapa 州[6]先後透過州立法，制定相關地方法規，Acur 州對於特定生物剽竊案件作出回應，而 Amapa 州則制定較廣泛的法案，致力永續發展，包括行使警察權力及特別專注在環境保護及教育[7]。

而巴西聯邦政府自 1995 年以來雖陸續提出相關草案[8]，但並未通過，於 2001 年 8 月 23 日始頒佈暫行措施[9]，共計 9 章，38 條。規定未經事前核准不得取得境內遺傳資源，申請取得遺傳資源者必須與遺傳資源所有人或代表人發表聲明所要取得之相關的遺傳材料，並須得主管機關、原住民社區、遺傳資源擁有者之 PIC。且若要進行商業使用，須簽署利益分享契約。若外國法人參與取得遺傳資源，更須與本國公立機構合作，研究工作亦宜在巴西境內進行。若對於探勘的地區有損害時應該要補償。並規定技術移轉之要件。從樣本或傳統知識所取得之經濟上利益，應以公平合理的方式分享。

4 印度

鑒於印度為生物多樣性及相關傳統知識豐富的國家，約佔全球生物多樣性約 7-8%[10]，生物多樣性權利實踐上歷經許多歷程[11]。為保護生物多樣性及使用遺傳資源時公平合理的利

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[4] 原文為西班牙文，*available at* ＜http://www.lclark.edu/org/ielp/costaricaspanish.html＞ (last visited May 3, 2005) 。本文所參照者為非官方英文翻譯版本，*at* ＜http://www.grain.org/brl_files/costarica-biodiversitylaw-1998-en.pdf＞ (last visited May 3, 2005)。

[5] Presidential Decree No. 31-514, 2003. 原文為西班牙文，*available at* ＜http://www.grain.org/brl_files/costa-rica-normas-accesos.pdf＞ (last visited May 3, 2005)。本文所參照者為非官方翻譯之英文版本，*at* ＜http://www.grain.org/brl_files/costa-rica-rules-access-en.pdf＞ (last visited May 3, 2005)。

[6] Amapa 州立法可參 http://www.lclark.edu/org/ielp/amapaenglish.html (last visited May 17, 2005)。

[7] *See* Jordan E. Erdos, *Current Legislative Efforts in Brazil to Regulate Access to Genetic Resources, at*＜http://www.planeta.com/planeta/99/1199brazil.html＞ (last visited Aug. 9, 2005).

[8] 如 Marina 參議員於 1995 年提出 On Access to Brazilian Biodiversity and Instruments of Control and Access to Genetic Resources 草案（Bill No 306/95）；行政機關亦於 1998 年 8 月向參議院提出法案；Deputy Jacques Wagner 亦於 1998 年提出修正案（Bill No 4579/98）以加速前開 Bill No 306/95 之通過，*see id.*。

[9] *Brazil - Provisional Measure No. 2.186-16 of August 23, 2001, at* ＜http://www.grain.org/brl/?docid=850&lawid=1768＞ (last visited May 17, 2005).

[10] *India Accounts For 7-8 % Of Earth's Biodiversity*, Oct. 20, 2004, *at* ＜http://timesfoundation.indiatimes.com/articleshow/894171.cms＞ (last visited Sept. 1, 2005).

[11] 有關印度在生物多樣性法制發展上之歷程，參 Shalini Bhutani & Ashish Kothari, *The Biodiversity Rights of Developing Nations: A Prospective from India*, 32 Golden Gate U.L. Rev. 587, 605-25 (2002).

益分享，因此制定 Biological Diversity Act 2002（2003 年 2 月 5 日生效）共計 7 章 65 條，為完整之生物多樣性立法[12]。。

其 ABS 制度區分非印度公民、法人及印度公民、法人而異其規定。若為非印度公民或法人，未經中央層級之國家生物多樣性機關（National Biodiversity Authority, NBA）[13]之事先核准，不得對遺傳資源進行研究或商業利用，或從事生物調查（bio-survey）或使用（bio-utilisation），不得為了商業考量而移轉研究結果給任何非印度公民或法人、組織[14]，亦不得對於來自於印度遺傳資源所得之研究或資訊申請智慧財產權（除根據國會制定的保護植物品種的法律所得以申請之權利外）。當國家生物多樣性機關核准申請時，得以課徵利益分享的費用、稅捐或條件。印度公民或法人（除原住民及社區外）則除非事先通知地方層級之州生物多樣性機關（State Biodiversity Board, SBB）[15]，不得對於遺傳資源從事商業利用、生物調查或生物使用。SBB 必須進行調查，並諮詢當地相關人之意見，決定是否符合要件，而予以核駁。另外重視地方社區之參與，當地社群則可組成生物多樣性管理委員會（Biodiversity Management Committees），NBA 及 SBB 在決定核駁前應徵詢其意見。

印度環境及森林部於 2004 年 4 月 15 日根據該法制定 Biological Diversity Rules 2004，進一步規定 ABS 制度相關程序，如各機關之組成與運作、執掌、取得遺傳資源及相連結之傳統知識之程序、核駁之標準、取得遺傳資源活動之限制、移轉研究成果之核准程序、申請智慧財產權前之核准程序、移轉給第三人之程序、公平利益分享之標準、如何使用國家生物多樣性基金、上訴機制等。

5 南非

南非原有的生物多樣性法制過於分散且不完全，其中大部分為省級層次的法規，缺乏全國一致性的立法。為了整合生物多樣性法制，統一各機關之事權，符合憲法的規定及加入 CBD 後之國際規範，並分配遺傳資源所取得之利益，南非於 2003 年制定 National Environmental Management: Biodiversity Bill（於 2004 年實施）。共計 10 章，106 條。

其中第 6 章規定生物探勘、取得及利益分享。規範目的在於管制對於固有生物資源[16]的生物探勘，及生物探勘後之遺傳資源出口，並建立公平合理的利益分享制度。任何人未經主管機關核准不得對固有生物資源從事生物探勘或出口。若牽涉到提供遺傳資源之人利益時，申請者必須向資源提供者揭露所有相關資訊，並獲得事先同意，與之締結材料移轉協議書（material transfer agreement）及利益分享協議書（benefit-sharing agreement）。前開兩種協議書都必須經過主管部部長批准才能生效。利益分享分配方式，則以材料移轉協議書及利益分享協議書所獲得之金錢建立生物探勘信託基金（Bioprospecting Trust Fund），再分配給資源提供者。未經核准擅自從事生物探勘屬犯罪之行為，並科以刑罰。

6 美國

美國雖非 CBD 簽署國，且為生物科技先進之已開發國家，然而其境內尤其是國家公園內，仍有豐富之遺傳資源，在其國家公園中從事科學研究採集標本，而取得遺傳資源已有

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[12] 有論者認為此法案回應了幾個重要議題，如生物科技與資訊科技的最新發展、隨著生物多樣性的遞減對於環境所產生之侵蝕與破壞、遺傳資源的經濟價值及印度政府對於 CBD 所揭示之主權原則及利益分享原則的嘗試，參 Madhav Gadgil, *India's Biological Diversity Act 2002: An Act for the New Millennium*, 28(2) J. BIOSCI. 145, 145-47 (2003), *at* ＜http://www.ias.ac.in/jbiosci/mar2003/145.pdf＞(last visited Jan. 22, 2005)。

[13] NBA 由中央政府指定之代表及專家所組成，掌管前開核准取得遺傳資源、移轉遺傳資源及申請智慧財產權事項及制定 ABS 規則等事項。

[14] 前兩種限制不包含合作研究計劃（collaborative research projects）。

[15] SBB 則由州政府指定之代表及專家組成，對於對州政府提出建言及核駁印度公民對於利用遺傳資源之申請。

[16] 所謂固有生物資源（indigenous biological resource）包括 1、任何固有物種之動物植物或其組織體，或以生物科技方式培養或改造之物。2、任何前開固有物種栽種之後代、變異體、萃取物、衍生物、雜交等型態。3、任何外來物種，利用生物科技已經改造成含有固有物種基因物質或化學成分。並排除人類基因物質、除前開含有固有物種基因物質及化學成分之外來物種外之外來物種及 PGRFA 所列之遺傳資源。

相當之歷史[17]，惟於 1916 年國家公園組織法（The National Park Services Organic Act）中始有以科學為目的之採集樣本之規範[18]。規定須由科學或教育機構提出申請，由主管機關審核是否符合科學及資源管理的目的，以決定是否許可申請。未經主管機關許可，不得採集植物、魚類、野生動物、岩石或礦物，且除非在國家公園以外的區域無法取得，及強化保護該物種，瀕臨絕種及受威脅之物種，不得核准申請。所採集之樣本尚須放置國家公園管理處博物館的標記並註冊。

雖然自國家公園採集遺傳物質進行研究，並獲致研究成果，然而長期以來並無條款確保研究成果所得之利益回饋予國家公園，迄於 National Parks Omnibus Management Act of 1998 中始有國家公園秘書處應與研究機構及私人企業就公平有效率的利益分享管理進行協商之原則性規定[19]。

另外在聯邦技術移轉法案（The Federal Technology Transfer Act of 1986, FTTA）中建立合作研究發展協定（cooperative research and development agreement, CRADA）[20]機制，由聯邦實驗室與私人間簽訂協定，聯邦實驗室可以在有補償或無補償的情形下提供人員、服務、設備或其他資源，而私人得以提供資金、人員、服務、設備或其他資源，共同進行特定的研究或發展[21]。

依據國家公園管理處 National Park Services Management Policies 2001[22]第 4.2.4 條之規定，除非得到特別法律授權或有效的權利，採集活體或非活體材料以進行商業產品的研究只有在限制的條件，及適當的聯邦授權下始得允許。此種採集只有在申請者簽署包含合理利益分享內容的 CRADA 才可被核准。

評析

由前開區域及各國對於 CBD 的實踐情形以觀，規範 ABS 制度之形式，雖有行政命令、暫行法、單獨立法或列於完整生物多樣性立法中之一章節等不同方式，且寬嚴不一，然均圍繞在強調主權、PIC、先經申請核准後，以締結協議方式取得遺傳資源，及利益分享等核心事項。

雖然 CBD 第 15 條第 2 項揭櫫會員國應努力創造條件，便利其他締約國取得遺傳資源用於無害於環境的用途，然而發展中國家在實踐上卻有限制甚至妨害其他締約國取得遺傳資源的趨勢[23]。對於這種嚴格取得遺傳資源條件，將遺傳資源國家化的趨勢，有學者憂心可能會造成二種風險，一為製造反共有（anticommons）[24]的風險[25]，二為侵害其土地或財產

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[17] 美國第一件核准在國家公園中進行採集標本始於 1872 年 3 月 1 日，由黃石公園核准在溫泉中採集微生物標本。多年以來持續有研究被核准，*see* WTO Doc., communication from the United States, *Access to Genetic Resources Regime of the United States National Parks*, IP/C/W/393 (Jan. 28, 2003), at 1-2。

[18] 36 C.F.R. § 2.5 (2001), *available at* ＜http://www.access.gpo.gov/nara/cfr/waisidx_01/36cfr2_01.html＞ (last visited June 5, 2005).

[19] National Parks Omnibus Management Act of 1998, Pub. L. No. 105-391, § 205(d), 112 Stat. 3497 (1998).

[20] *Benefit-Sharing in the National Parks Environmental Impact Statement, at* ＜http://www1.nature.nps.gov/benefitssharing/legal.htm＞ (last visited May 17, 2005).

[21] *See* 15 U.S.C. § 3710a (2004), *available at* ＜http://www4.law.cornell.edu/uscode/html/uscode15/usc_sup_01_15_10_63.html＞ (last visited Sept. 1, 2005).

[22] *See "Things to Know": ...about National Park Service Policy and the Directives System, at* ＜http://www.nps.gov/policy/DOrders/thingstoknow.html＞ (last visited May 17, 2005).

[23] 造成此種趨勢之原因，其一為對於已開發國家賦予遺傳物質或生物科技產品專利權日益增加的回應，其二則是環保團體的鼓吹，環保團體認為透過給予遺傳資源國金錢的方式可以促使該國保育受威脅的環境。*See* Sabrina Safrin, *Hyperownership in A Time of Biotechnology Promises: The International Conflict to Control the Building Blocks of Life*, 98 AM. J. Int'l L. 641, 648-49 (2004).

[24] Anticommons 係指當一個有限的資源，而有過多的個體擁有排他的權利或決策權，會使之不經濟，參 Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition form Marx to Markets*, 111 HARV. L. REV. 621, 622,625,677 (1998).

[25] 如前開菲律賓法制，申請者必須要得到不同層級的政府機關審查及同意，申請者亦必須符合對於原住民社區或地方政府之事先知情同意；就 OAU 的模範法，必須得到政府及地方社區之事先知情同意；就 ASEAN 草

上具有遺傳資源之個人或原住民社區的自主權之風險[26]。從而倘為了確保能夠真正反應原住民及社區之觀點，則須採取如前開菲律賓、OAU 等多重合意（multi-consent approach） 立法方式，然而卻會造成反共有的情形，若為了防止反共有的情形，由國家機關代為行使同意權，又可能弱化或侵害原住民或社區之自主權，形成兩難局面，如何制訂既經濟又能反映原住民及社區意見之制度，為發展中國家需努力克服之議題。

又 CBD 雖然採取將遺傳資源視為如石油、原木等有形資產來看待，國家對之具有主權，甚至擁有所有權，然遺傳資源雖然由有形的化學物質所組成，但其有價值的部分並不在於特定細胞，而是蘊含在眾多細胞中之資訊，特性較似無形物質，此種特性導致原產地難以確定，進而使申請者將向誰提出申請，應獲得何人之 PIC，利益又將分享與何人亦難以確定[27]。另外將遺傳物質大部分潛在利用價值留在資源提供國境內在執行上極為困難，防堵的成本很高，因此許多協定及內國法制遂有反過來限制智慧財產權，以實現限制取得遺傳資源制度之趨勢[28]。面對此種趨勢，內國 ABS 制度，應如何與其國內智慧財產權制度相調和，是否能以 ABS 制度回應已開發國家擴張智慧財產權之腳步，亦值得進一步探究。

綜觀遺傳資源豐富之開發中國家為因應非法生物探勘及生物剽竊，及先進國家擴張賦予遺傳資源智慧財產權之現象，已陸續制訂 ABS 制度，強調國家對於遺傳資源之主權，訂定取得遺傳資源程序性規定，並提出利益分享制度，前述區域協定及內國法制似應足以避免不公平生物探勘及生物剽竊問題。然而其 ABS 制度是否過於嚴格，因而阻礙生物科技研發，以致無法達到 CBD 之原始立法目的，使遺傳資源無法發揮其最大效用，即值得慎思。

此外，並特別就 PIC 制度與各國實踐予以初步之論證與評析： "The Use of Prior Informed Consent to Ensure a Fair and Equitable Access to Genetic Resources: A Comparative Study and Taiwan's Response" 發表於「台灣基因意向之調查與研究」學術研討會，中央研究院人文社會科學研究中心主辦，民國 95 年 5 月 10 日。未來在進一步充實其內容後，將投稿於國內外期刊。

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案，亦規定申請者必須符合對於政府及地方政府的事先知情同意，亦須與所有資源提供者，尤其是原住民及地方社區協商利益之分配。*See* Safrin, *supra* note 23, at 654-55。

[26] 若生物探勘計劃將使國家獲取利益，則蘊含國家將強迫原住民或社區同意此計劃之潛在危機。潛在危機如巴西前開暫行法，規定當牽涉到公共利益時，政府可以不經過原住民或原住民社區之同意，逕行私人土地採集樣本（genetic heritage），*id*. at 658。又即便國家對於遺傳資源並無排他的利益，然而為了確保利益分享，如巴西及印度即採取由國家機關集中控制（paternalism model）之方式，亦減弱原住民及社區對於遺傳資源之控制，此種情形在兩者利益有衝突時更加明顯。*Id.* at 659-60.

[27] *Id*. at 664-65.

[28] 如印度規定若未得到 NBA 之事先核准，任何人不得對基於在印度境內之遺傳資源所做成之研究所得之發明申請智慧財產權，若核准亦得課徵利益分享之費用或稅捐；巴西暫時性措施亦規定申請專利或智慧財產權必須標示原產地；哥斯大黎加及安地斯社群則將智慧財產權制度與取得遺傳資源法律相連結；OAU 則規定若未經資源提供者之事先知情同意，不得申請任何形式的智慧財產權。*Id.* at 666.

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三、計畫成果自評

已大致完成各主要國家遺傳資源管理法制，特別關於 ABS 制度之整理、歸納與分析。並提出其缺失之初步觀察；此外，並已完成哥斯大黎加遺傳資源管理之參訪及報告。此成果皆可以作為我國未來思考有關立法及管制之借鏡。故大致符合此連續性計畫第一年預期之工作目標。相關研究並已發表於法學期刊及研討會。未來工作將對於遺傳資源管理法制之特定議題，如利益分享、智慧財產權等進行更深入之比較及研究。

四、附錄

The Use of Prior Informed Consent to Ensure a Fair and Equitable Access to Genetic Resources: A Comparative Study and Taiwan's Response[*]

[*] This paper is simply at a preliminary stage. Please do not cite the work without the author's permission. This paper

Kuei-Jung Ni[**]

Contents

Abstract

There has been increasingly international awareness, mainly from developing countries, of mandating a proper control on illegal bio-prospecting of genetic resources during the past decade. The Convention on Biological Diversity (CBD) adopted in 1990s has been widely viewed as a powerful international mechanism in dealing with the issue mainly by requiring access to and benefit-sharing (ABS) regime in the national level. The prior informed consent (PIC) specified by the treaty constitutes a major means to deter the infamous unregulated bio-piracy and to ensure a fair access to genetic resources.

Since the effectiveness of the CBD, national implementation of the ABS has been flourishing, shown in the enactment of laws and regulations. Given the differential social structure in individual nations, there seems no consistent pattern of the PIC practices domestically. Some legislatures recognize the decisive role of indigenous or local community in the context of enforcing PIC, making access to genetic resources impossible without their consent. On the other hand, to ensure the access process more effectively, several central governments dominate PIC process so as to make the will of local people relatively margin or simply to treat their determination only as one of the factors to be considered for the final decision of granting consent.

This article aims to conduct a comparative study on how genetically rich nations implement the PIC requirement with a view to examining whether the genuine objective of the CBD has been fulfilled. The task involves an analysis of legal arrangements and implications in several leading models of legislature. Recently, Taiwan has started to sense the significance of regulating the bio-prospecting activities and to engage in formulating a draft thereafter. It thus will be a focal point of this article to evaluate the normative design of the PIC in such a law.

Keywords: Genetic Resources, Bio-piracy, CBD, Access and Benefit-sharing, Prior Informed

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was attributed to the financial support from the National Science Council (NSC 94-2414-H-009-001-).

[**] Associate Professor of Law, Institute of Technology Law, National Chiao Tung University.

I. Background: The Consolidation of Movement to Control Genetic Resources

In wake of the development of biotechnology, the value and significance of biogenetic resources has appeared increasingly prominent, playing a significant role in the sphere of world agriculture, food security and the global economy.[29] Normally, the value of genetic resources (GR) can be found in plants, insects, animal or microbial. As a result, human or animal genes are literally excluded from the context of GR.[30] In addition, the accomplishment of the GR value would involve many stages, including bio-prospecting, sampling, testing, and other scientific steps.

It seems that a variety of stakeholders, nationally or internationally, may have relevance or interests in generating the value of GR. Admittedly, indigenous people or local communities could have more solid ground to claim the right of GR, given the use of GR usually has become an integral part of their traditional life and cultural.[31] Bio-prospecting researchers or companies may assert the justification to access to GR simply because the value of GR cannot be disclosed without the assistance of advanced bio-technology. Therefore, their freedom of bio-prospecting and research should be respected.[32] Of course, nations may find an indispensable role in regulating activities occurring within their boundary, including exploration on GR. On the other hand, there have insistence of putting GR under international control to ensure that the interests of GR may be available or accessible to all human kind instead of being only dominated by sovereign regime.

It was true that the move to classify GR as international common property had been initialed by one international organization. The primary effort of the United Nations Food and Agriculture Organization (FAO) in preserving agricultural genetic resources represents a leading model. In 1983, the International Undertaking on Plant Genetic Resources (Undertaking) was adopted, which specifies that the Undertaking "is based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction."[33] The move at the earlier stage was designed to ensure the interests of GR not to be monopolized by private sectors, but should benefit all humans.[34] In practice, the concept of GR as a part of common heritage of mankind (CHM) would prevent national government from regulating access to GR and make the resources a freely accessible products.[35]

Irrespective of the idealism of equating GR with the CMH, it is doubtful to assert the prevalence of the doctrine, particularly, in light of the current development. First of all, the Undertaking, a soft law, by nature is not legally binding instrument. Secondly, the idea of GR as part of CHM is hardly practiced by either developed or developing nations. The former initially made reservation to the idea promoted by the Undertaking.[36] It is also clear that the doctrine of global genetic commons has no longer honored by the latter. Rather, the developing world tends to argue that the GR should be under sovereign domain and to favor a strong and effective national regulation and control of access to GR within their territory.[37] Third, the global commons of GR would meet difficulties in management. As most GR, apart from located in the

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[29] See generally Graham Dutfield, Intellectual Property Rights, Trade and Biodiversity, London: Earthscan, 2000, at 1 Mitsuo Matsushita *et al*, The World Trade Organization: Law, Practice and Policy, Oxford: OUP, 2003, at 413.

[30] According to Art. 2 of the CBD, the agreement define GR as "genetic material" of actual or potential value. Genetic material means "any material of plant, animal, microbial or other origin containing functional units of heredity."

[31] See Michael I Jeffery, *Bioprospecting: Access to Genetic Resources and Benefit-Sharing under the Convention on Biodiversity and the Bonn Guidelines*, 6 Sing. J. Int'l & Comp. L. 791 (2002).

[32] There are growing criticism from scientists and academic researchers regarding the tighten control of access to GR by national governments. See New York Time; See also Jeffery, supra note, at 793.

[33] Available at FAO website

[34] Jeffery, supra note, at n. 58 (The author further observes the failure of the Undertaking to achieve its primary purpose).

[35] See Sabrina Safrin, Hyperownership in a Time of Biotechnology Promises: The International Conflict to Control the Building Blocks of Life, 98 Am. J. Int'l L. 644-45 (2004).

[36] Id. n. 15.

[37] Jeffery, supra note, at 759.

High Sea, is within certain countries' boundary, the internationalization of GR will definitely encounter resistance from those sources providing nations. The difficulty to attempt to regulate deep sea bed under international control simply provides a vivid case.[38]

As the idea of a global genetic commons seems obsolete and no longer effective, there has been a growing tendency to switch a global commons approach to sovereign dominance approach on GR control during the past decades. In particular, developing countries voiced their objection and anger to bio-piracy or illegal bio-prospecting activities occurred in their nations.[39] They considered a tighter regulation on access to GR and a fair benefit-sharing out of using GR are essential to deter unjust and assure equity.

Apparently, the conclusion of the Convention on Biological Diversity (CBD) in 1992 had echoed the call for a proper control on GR mainly by requiring a fair and equitable sharing of GR interests as one of its three objectives.[40] On the authority and competence to regulate access to GR, the CBD entrusts the power to contracting party by reaffirm the sovereign rights of State on GR.[41] Although the skepticism to the confirmation of the prerogative of States by CBD is understandable,[42] the sovereign control of GR arguably could be underpinned by firm evidences of customary international environmental law.[43] Further, given the wide support of CBD[44] and irreplaceable function of national governments, it is of a prevailing trend that national authority has played as a central and governing role in regulating genetic resources.

More important, the treaty underlines provisions of access to and benefit-sharing (ABS) of GR. Nowadays, the ABS regime in general has been considered as a powerful mechanism to maintain fair access to GR and to deter infamous bio-piracy. The device of prior informed consent (PIC) is also incorporated as one of critical elements within ABS. The PIC represents the termination of the used practice of "free access" that paid no respect to the will of nations providing GR. The mechanism is considered a major means to ensure a "fair access" to GR.

In practice, as political and social structure in individual nations differs, there seems no consistent pattern of domestic PIC practices. Some legislatures recognize the decisive role of indigenous or local community in the context of enforcing PIC, making access to GR impossible without their consent. On the other hand, to ensure the access process more effectively, several central governments largely dominate the PIC process so as to make the will of local people relatively margin or simply to treat their determination only as a reference for the final consent granting.

The increasing global concern over the GR's access system is unable to create a satisfactory outcome without the proper enforcement on a local basis. This article is thus designed to engage in a comparative study on how genetically rich nations implement the PIC requirement mainly by examining their legislations. While the enactment of the GR access rule in Taiwan has become imminent, the current legislative move in this regard will also be reviewed.

II. The Concept of PIC

A. Original meanings and function

The informed consent constitutes a cornerstone in the patient-physician relationship. The physicians are obliged to "disclose information to the quality of a patient's or subject's

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[38] According to article of the UN Law of the Sea Convention, the status of the deep sea bed of the High Sea amounts to CHM.

[39] Bad patent issue,

[40] CBD, Art. 1. The other two objectives of the CBD include "the conservation of biological diversity and the sustainable use of its components." Id.

[41] CBD, Art.15(1).

[42] See generally Safrin, supra note, at 652-63.

[43] It has become a customary rule of international environmental law that States are entitled to claim sovereign rights on natural resources within their jurisdiction. See Birnie & Boyle, International Law and the Environment (2nd ed.), Oxford: OUP, 2002, at 112-14. A numerous international documents of the environment specify the rule, such as 1972 Declaration of the UN Conference on the Human Environment, Principle 21; 1992 Rio Declaration, Principle 2; 1982 United Nations Convention on the Law of the Sea (UNCLOS), which explicitly recognize the sovereign rights of States on their Exclusive Economic Zone and Continental Shelf.

[44] CBD currently has 188 contracting parties. See CBD website: <http://www.biodiv.org/world/parties.asp> (last visited on April 15, 2006). However, the USA and Taiwan are the two major nations who are non-contracting parties.

understanding and consent."[45] The patients shall be entitled to be informed of any risk and consequence of medical treatment. In addition, the treatment cannot proceed without his or her consent.

The primary rational for the informed consent aims at minimizing risk and "avoiding unfairness and exploitation".[46] However, it is observed that the current justification for informed consent has evolved to protect patients' and subjects' autonomy rights.[47]

The elements of informed consent could comprise the following components in the sequence of how the informed consent proceeds: (1) competence, (2) disclosure, (3) understanding, (4) voluntariness, and (5) consent.[48]

The spirit of PIC has also been incorporated in international rules dealing with transboundary substance that may cause risks or potential harm to national or local environment. For instance, the Basel Convention requires that hazardous wastes shall not be exported without a written consent from importing State.[49] Upon the receipt of the notification of the intent to export the wastes, the State of import may respond to the request by consenting, denying the transboundary movement or inquiring additional information.[50] The recent effectiveness of the Cartagena Protocol on Biosafety is of significance in regulating international movement of Living Modified Organisms (LMOs). To safeguard the domestic health and environment, the Protocol takes a similar mechanism as that of the Basel convention, requiring an advance informed agreement (AIA) before the transboundary movement of LMOs.[51] The procedure to secure an AIA also mirrors the rules of the Basel convention.[52]

B. The Device of CBD Regime and Supervening Development of the Bonn Guidelines

Under the age of free access to GR, generally speaking, neither national governments were informed any bio-prospecting conducted within their border nor indigenous people or local communities. By the same token, the bio-activity had been conducted without the approval or consent of stakeholders in questions. Any bio-prospecting, irrespective of its potential contributions to the reveal of the value of GR, is likely to cause damage to national conservation as a whole and indigenous tradition as well without a proper control. Thus, the ABS of the CBD mandates the spirit of PIC, providing that "Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party."[53] The CBD, as a general framework, as opposed to defining the term of PIC, seems simply to declare its intention to require a PIC in access process. But, no detailed substance of the element has been provided in the context.

Thus, much room needs to be filled in with respect to the legal content and implications of PIC in this regard. For instance, the following issues[54] may be of critical importance and need to be further elaborated:

1. Who is entitled to grant the consent: local community, private owner, or national authority? The PIC is a single consent-giving system? Or it should hinge on multi-subject of consent granting?
2. What information should be delivered by GR users?
3. What the role of a PIC should play in the context of access to GR?

At its Sixth Conference of the Parties (COP), CBD, after intense negotiations, proclaimed a

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[45] Tom L. Beauchamp, James F. Childress, Principles of Biomedical Ethics (5th ed.), New York: OUP, 2001, at 77.
[46] Id.
[47] Id. See also Robert M. Veatch, The Basics of Bioethics (2nd ed.), New Jersey: Prentice Hall, 2003, at 72.
[48] Beauchamp & Childress, supra note, at 79.
[49] Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, adopted March 22 1989, in force May 5, 1992. Art. 4 (1) (c).
[50] Id. Art. 6 (2).
[51] Cartagena Protocol on Biosafety, adopted Jan 29, 2000, in force Sep. 11, 2003. Art. 7.
[52] Id. Art. 8-10, 12.
[53] CBD, Art. 15(5).
[54] See Laurel A. Firestone, You Say Yes, I Say No: Defining Community Prior Informed Consent under the Convention on Biological Diversity, 16 Geo. Int'l Envtl. L. Rev. 185 (2003); Jeffery, supra note, at 786.

detailed document of the Bonn Guidelines[55] that may assist nations to have an effective implementation of the ABS mandate. Concerning PIC, the Guidelines first specify *basic principles* of a PIC system, which includes:

a. Legal certainty and clarity;
b. Access to genetic resources should be facilitated at minimum cost;
c. Restrictions on access to genetic resources should be transparent, based on legal grounds, and not run counter to the objectives of the Convention;
d. Consent of the relevant competent national authority(ies) in the provider country. The consent of relevant stakeholders, such as indigenous and local communities, as appropriate to the circumstances and subject to domestic law, should also be obtained.[56]

The application of the principles of legal certainty, economy, and transparency in PIC may ensure national GR access system to facilitate bio-prospecting and to avoid unnecessary barriers and restrictions to GR prospective users.[57] Moreover, principle (d) clearly states that competent national authorities are the main entities that grant consent to applicants for a GR access.[58] On the other hand, the principle tends to recognize that relevant stakeholders, such as indigenous and local communities, may play a role in the consent granting. The move that takes into account the right of stakeholder to participate PIC is of significance and progress. But, their consent seems not as decisive and essential as that of national authorities, given the power is to be constrained by the phase "as appropriate to the circumstances and subject to domestic law."[59]

In addition, some *elements* of a PIC system are suggested as follows:

a. Competent authority(ies) granting or providing for evidence of prior informed consent;
b. Timing and deadlines;
c. Specification of use;
d. Procedures for obtaining prior informed consent;
e. Mechanism for consultation of relevant stakeholders;
f. Process.[60]

The element (a) elaborating basic principle (d) indicated above reiterates that a PIC application, in principle, shall be obtained from central status of competent national authorities.[61] Meanwhile, the authorities in governing PIC system are requiring to respecting legal rights of indigenous and local communities associate with the GR being accessed.[62]

In particular, the element (d) of "procedure for obtaining prior informed consent" further underlines constructive clues on what information should be provided by GR access applicants. The suggested list contains the following items:

a. Legal entity and affiliation of the applicant and/or collector and contact person when the applicant is an institution;
b. Type and quantity of genetic resources to which access is sought;
c. Starting date and duration of the activity;

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[55] "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization," *Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity*, U.N. Doc. UNEP/CBD/COP/6/20, Decision VI/24 (A), at 262 (May 27, 2002), *available at* <http://www.biodiv.org/doc/decisions/COP-06- dec-en.pdf> (last visited Apr. 20, 2006) [hereinafter Bonn Guidelines].
[56] Id. para. 26.
[57] See also Jeffery, supra note, at 797.
[58] See also Bonn Guidelines, supra note, paras.15, 28, 32.
[59] See also id. para. 31.
[60] Id. supra note, para. 27.
[61] Id. para. 28.
[62] Id. para. 31.

d. Geographical prospecting area;
e. Evaluation of how the access activity may impact on conservation and sustainable use of biodiversity, to determine the relative costs and benefits of granting access;
f. Accurate information regarding intended use (e.g.: taxonomy, collection, research, commercialization);
g. Identification of where the research and development will take place;
h. Information on how the research and development is to be carried out;
i. Identification of local bodies for collaboration in research and development;
j. Possible third party involvement;
k. Purpose of the collection, research and expected results;
l. Kinds/types of benefits that could come from obtaining access to the resource, including benefits from derivatives and products arising from the commercial and other utilization of the genetic resource;
m. Indication of benefit-sharing arrangements;
n. Budget;
o. Treatment of confidential information.[63]

Of course, as indicated by the Guidelines, the list of information is of optional nature. The use of which may be adapted to national special needs.[64]

Although the Bonn Guidelines that aims to help parties build their capacity in implementing ABS system is literally not legally binding, it does provide countries very useful reference. Its influence on national practices and legislatures thus cannot be underestimated.

Overall, the PIC system suggested by the Bonn Guidelines tends to confirm the primary legal capacity and indispensable role[65] of national authority in governing PIC, while allowing nations to maintain the discretion to determine what the status of relevant stakeholders is in the consent-giving process. On the other hand, in balancing the power of granting PIC delegated to competent national authorities, the Bonn Guidelines also expect the regime to be responsible for granting access and advising on certain matters.[66]

III. National Practices on PIC Requirement: some leading cases' study

Since the inception of the CBD and the supervening adoption of the Bonn Guidelines, many developing countries with rich genetic resources have enacted national laws implementing ABS regime.[67] This study manages to single out a number of leading national practices as follows:

A. India

[63] Id. para. 36.
[64] Id.
[65] Jeffery, supra note, at 798-99.
[66] Para. 14 of the Bonn Guidelines provides:
Competent national authorities, where they are established, may, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access and be responsible for advising on:

a. The negotiating process;
b. Requirements for obtaining prior informed consent and entering into mutually agreed terms;
c. Monitoring and evaluation of access and benefit-sharing agreements;
d. Implementation/enforcement of access and benefit-sharing agreements;
e. Processing of applications and approval of agreements;
f. The conservation and sustainable use of the genetic resources accessed;
g. Mechanisms for the effective participation of different stakeholders, as appropriate for the different steps in the process of access and benefit-sharing, in particular, indigenous and local communities;
h. Mechanisms for the effective participation of indigenous and local communities while promoting the objective of having decisions and processes available in a language understandable to relevant indigenous and local communities.

[67] India, Brazil, Costa Rica, Andean group, ASEAN nations and the Organization of African Unity have passed the laws. *See generally* Safrin, supra note, at 641, 649 and n. 56 (2004).

Enacted in 2002, the Biological Diversity Act[68]of India represents a very recent legislation aiming at fully implementing CBD mandates.[69] To echo the call of the Bonn Guidelines in establishing a competent national authority, the law creates the "National Biodiversity Authority" (NBA)[70] responsible for, *inter alia*, regulating resources[71] access activities. Any foreigners are prohibited from obtaining any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization without the previous approval of the NBA.[72]

With respect to the participation of stakeholders in PIC system, the India law simply requires the NBA to engage in "consultation" with local biodiversity committees.[73] The NBA thus remains the authority in consent granting. Further, there is no role of individuals, indigenous or local groups in the India PIC granting process. The vacancy of those stakeholders' will in the approval of an access application marks the single-consent nature of the India statute. The access regime is also a typical model of the centralization of GR control in quite broad sense by national government.[74]

Strictly speaking, the India law negating the role of other civil GR providers would not be considered incompatible with the CBD or the Bonn Guidelines that does not explicitly recognize the consent right of those parties. However, the deprivation of the privilege of those parties to participate in the decision-making of a PIC appears a deviation from the objective of the CBD. Also, "the paternalistic model," as Safrin contends, is likely to create a risk to "the autonomy and interests of individuals and indigenous communities. . ."[75]

B. Brazil

Brazil in 2001 adopted a "Provisional Measure"[76] that aims at regulating not only GR (genetic heritage)[77] access, but also protection of and access to associated traditional knowledge (TK). The code also concerns the transfer of technology relating to conservation and use of GR and TK.[78] Thus, the law is a quite broad move in implementing CBD mandate regarding GR, irrespective of the interim nature of the legislation.

The Provisional Measure creates the Council for the Management of Genetic Resources under the Ministry of the Environment as a CAN that is responsible for the authorization of a GR access.[79] In particular, such an approval can only be given to a domestic public or private institution,[80] which appears to exclude foreigners from conducting bio-prospecting in Brazil. The discriminatory policy could be questioned as a violation of article 15(2) of the CBD that requires nations housing GR to facilitate GR access for foreign bio-prospectors.

While the Council governs the approval of a GR access application, the code recognizes the status of GR "owners" in a manner that the authorization cannot be granted without the PIC of relevant stakeholders. The parties who may give consent thus are quite multiple, including public and private entities. For endangered species from which a GR would be accessed, a PIC must be

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[68] Biological Diversity Act, 2002, No. 18, Feb. 5, 2003, available at <http://envfor.nic.in/divisions/biodiv/act/bio_div_act.htm>.

[69] The preamble to the Act explicitly indicates a close linkage of the law to CBD. See id.

[70] Id. §§8, 18.

[71] In terms of ABS system, the natural resource of life governed by the India law is broader than that of the CBD. The former refers to "biological resources," which means "plants, animals and micro-organisms or parts thereof, their genetic material and by-products with actual or potential use or value." Id.§ 2(c). By contrast, the CBD's access regime covers GR only.

[72] Id. §3(1).

[73] Id. §41(2).

[74] See Safrin, supra note, at 659-60.

[75] Id. at 652, 659-60.

[76] Provisional Measures, No. 2.186-16 (August 23, 2001). Authorized by Article 62 of the Brazilian Constitution, the President of Brazil has the power to adopt the Provisional Measure.

[77] The Brazil law that applies genetic heritage rather than genetic resources focuses the "information of genetic origin". The range of the Brazilian regulation seems broader than that of CBD. Id. Art. 7 (I).

[78] Preamble to the Provisional Measure. Id.

[79] Id. Art. 10, 11.

[80] Id. Art. 16.

obtained from the competent body.[81] Otherwise, the interested parties who are entitled to give a PIC including the following:

1. The *indigenous community* involved, the views of its official representative body having been heard where access occurs on indigenous territory;
2. The *competent body* where access occurs in a protected area;
3. The *owner* where access occurs on *private land*;
4. The *National Defense Council* where access occurs in an area indispensable to national security;
5. The *maritime authority* where access occurs in Brazilian territorial waters, on the continental shelf or in the exclusive economic zone.[82]

However, exceptionally, a public interest defined by the Management Council may prevail over the will of the stakeholders specified above. Therefore, their PIC is not a requirement for access authorization.[83]

Although Brazil generally speaking explicitly gives stakeholders the right of PIC, national authority remains the final decision-making on GR access system. The centralization of GR access, not surprisingly, was accused of causing adverse effect on the inherent interests of individuals and indigenous people.[84] But, the practice of Brazil has taken into account the position of GR interested parties as opposed to want of any PIC from other stakeholders apart from national authority provided in India Law.

C. ASEN[85]: the Philippines

The initial regulatory attempt of the Philippines on GR bio-prospecting could be regarded as one of the earliest national legislatures swiftly responding to CBD's call for incorporating ABS requirement. The country in 1995, even while the Bonn Guidelines had not yet been adopted, primarily issued an executive order No. 247(EO)[86] aiming at "Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By-products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes."

It is the Inter-Agency Committee on Biological and Genetic Resources that is responsible for the enforcement and implementation of the EO.[87] The Committee under the Department of Environment and Natural Resources is composed of representatives of relevant governmental agencies.[88] The approval of the Bio-prospecting depends on recommendation of the Committee and a mutual agreed research agreement between applicants and the Philippe government.[89]

In particular, the EO perhaps represents a role model of legislature that is extremely keen to honor the interests of indigenous people and local communities in PIC process. The law so values the status of those groups that it sets out a special clause of "Consent of Indigenous Cultural Communities" in the very beginning of the law, requiring a PIC of such communities as a prerequisite for the authorization of bio-prospecting activities.[90] A research proposal prepared by applicants shall also be delivered to leaders of those communities and duration up to 60 days for deliberations is required before a decision on the application would be made.[91] Furthermore, it is the duty of the Inter-Agency Committee to ensure the rights of indigenous and local communities are protected. The Committee is also obliged to stipulate guidelines implementing the PIC, which

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[81] Id. Art. 16(8).
[82] Id. Art. 16(9)[emphasis added].
[83] Id. Art. 17.
[84] Safirn, supra note, at 658-60.
[85] The Association of South East Asian Nations in which the Philippines is a member concluded the Framework Agreement on Access to Biological and Genetic Resources in 2000, which on PIC mandates all resources providers, nationally and locally, be involved in the process. Id. Art. 10.
[86] Executive Order No. 247. (May 18, 1995) [hereinafter EO].
[87] Id. Sec. 6.
[88] Id. Apart from DENR, the other agencies involves the function of the Committee includes the Department of Health, Agriculture, Science and Technology, Foreign Affairs and National Museum. Id.
[89] Id. Sec. 3.
[90] Id. Sec. 2.
[91] Id. Sec. 4, para. 3.

may assist the communities to have a better PIC performance.[92]

While the EO gave full consideration to the right of indigenous people over PIC, the interests of other stakeholders have been addressed by the EO's Implementing Rules and Regulations.[93] The PIC shall be secured from subjects, including local community, IP [Indigenous Cultural Comminutes or Indigenous People], PAMB [Protected Area Management Board] or Private Land Owner.[94] The rules also require a full disclosure of "the intent and scope of the bioprospecting activity, in a language and process understandable to the community, …"[95]

The procedure to obtain a PIC from communities was considered to be burdensome and made applicants difficult to identify which community is entitled to give consent. A commentator is skeptical on the multiple consent system that may create a risk of anticommons.[96]

The strict process of obtaining a PIC to some extent has been alleviated by subsequent enactment of the "Wildlife Resources Conservation and Protection Act" of the Philippines.[97] While the multiple consent system remains a requirement in accordance with existing laws, the 60-day waiting duration has been replaced by "a reasonable period.[98]"

IV. Taiwan's Response to the Challenge

A. Rich Genetic Resources in Taiwan and Her Unpleasant Experience As a Result of the lack of a Proper Regulation

Taiwan has the reputation for her abundant GR, although the territory of Taiwan only occupies 0.03% of the Earth land. There are 6,000 plant species in Taiwan that accounts for 2.1% of the world plants. The 29,000 animal species represents 3.4% of the Earth animals. Taiwan has also more than 10,000 micro-organisms accounting for 8.6% of the world.[99]

The wealthy bio-resources of course may draw the attention of bio-prospectors. While some statistic shows many foreigners, individuals or institutions or companies have been conducting the exploration of GR for academic or commercial purpose during the past few decades, no legal system has yet been formulated in dealing with management of the activities.[100] Unfortunately, Taiwan has experienced unpleasant outcome caused by unregulated, uncompensated GR access activities due to the lack of a proper control on legal basis.

For instance, the Paclitaxel extracted from trees grown in Taiwan has been proved effective in treating cancer, especially of the female disease. The medicine under patent protection has generated huge commercial interests. But, the original collection of the genetic material was conducted without the permission of Taiwan and of course the country was unable to share any benefits of the commercialization of the drug.

The plant "Nothapodytes nimmoniana (Graham) Mablerley"[101] that may be able to cure cancer provides another vivid case. The plant was found in Lan-yu, an offshore indigenous island of Taiwan. A Japanese company was bringing it to the southern part of Taiwan to have local farmers grow it as they explored the medical effect of the plant. The company had then been extracting the compound of it and subsequently has been awarded a number of patents around the world.[102] It perhaps is not a typical case of a bad patent because of the unavailability of local art

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[92] Id. Sec. 7(e).
[93] Philippine Dep't of Env't & Nat. Res., Admin. Order No. 20 (July 9, 1996).
[94] Id. Sec. 2.1(W).
[95] Id.
[96] Safrin, supra note, at 653-54. The anticommon refers to a non-economic outcome where too many entities own exclusive rights or decision-making powers over limited resources. See Michael A. Heller, The Tragedy of the anticommons: Property in the Transition from Marx to Markets, 11 Harv. L. Rev. 621-23 (1998).
[97] Wildlife Resources Conservation and Protection Act, Rep. Act No. 9147 (July 30, 2001).
[98] Id. Sec. 14, para. 2.
[99] See generally Warren H. J. Kuo et al ed., Access and Benefit-sharing of Genetic Resources, Taipei: NTU Department of Agronomy, at 36 (2005).
[100] Id. at 38.
[101] See <http://www.ttdares.gov.tw/ttdares/to22.html> (last visited July 4, 2005).
[102] The development of the event *available at* <http://ult.idv.tw/modules/newbb/viewtopic.php?forum=14&topic_id=188&post_id=1297&viewmode=thread&order=0> (last visited Aug. 15, 2005).

or knowledge prior to finding the value of the plant. But, apart from the local farmers, Taiwan as a whole has never benefited from the vast commercial interests arising from the invention. Thus, Taiwan has also been damaged as a result of lacking proper control of accessing to genetic resources, although the unfairness has no connection with the plant of patents.

B. The Status of Taiwan in the Context of the CBD Regime[103]

It is submitted that the CBD regime has proved the most influential international institution governing biological diversity mainly because most countries in the world are contracting parties and are implementing CBD mandates, especially regarding ABS elements. There are only two major nations who have yet acceded to CBD. The U.S. chooses not to join the regime. Given the unique status of Taiwan, she is currently not allowed to join most multilateral environmental agreements (MEAs) that generally require Statehood as the qualification for their membership. Since, as indicated above, the sovereign control of GR specified in the CBD reflects customary international rule, Taiwan, as a subject of the international communities, irrespective of her unsettled status, does enjoy the jurisdiction over GR control. Taiwan's non-contracting party to the CBD therefore cannot deprive her capacity to engage in the building of relevant ABS legal system. It is also the author's belief that no countries would make a protest to Taiwan's determination and policy to control GR.

C. The Move to Regulate ABS on Genetic Resources: the state of play on PIC

In 2001, the Executive Yuan of the Taiwanese government adopted the "Measure to Enforce Biological Diversity", calling for the enactment of the GR law.[104] In light of national practice in the world, there are two types of GR legislative model. The first model adopted by India, Costa Rica and the Philippines is to formulate a comprehensive biological diversity law that may largely echo most of the elements of the CBD. Of course, GR access would be a part of it. Otherwise, countries may opt for a specific law on GR access or management only. As indicated above, nations, such as Brazil, took the approach.

In pondering which model is more appropriate for Taiwan, it is submitted that the conclusion of a general biodiversity law may meet difficulty in accommodating the current Taiwanese legal systems that have already governed national park, forest, wild animals, indigenous people and cultural asset preservation.[105] The complexity and relatively heavy cost embodied in such an attempt dissuaded decision-makers from enacting a law covering every aspect of biodiversity.[106] Therefore, a consensus has been reached at concluding an individual statute on the GR access.[107]

During 2005, a drafting team comprising legal and biologic professionals was organized and coordinated under the leadership of Professor Kuo at National Taiwan University. After a number of intense consultations and meetings,[108] a draft of the GR law that focuses on ABS regulation was finalized in the end of 2005.

Generally speaking, the law, in contrast to those of India and Brazil, provides an equal treatment between foreign and national applicants, governing the behavior of bioprospecting itself irrespective of the nationality of applicants.[109] Instead of establishing an inter-agency, the Council of Agriculture, is delegated the major competency.[110] It further requires all GR access applicants to obtain permission from the competent authority.[111]

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[103] The general study of Taiwan's Status in the International Environmental Law see Kuei-Jung Ni, The Status of Taiwan in International Environmental Law, 31 (2) National Taiwan University Law Journal 97-130 (2002).

[104] "Measure to Enforce Biological Diversity", the Executive Yuan Meeting, 2747 (Aug. 15, 2001). The Council of Agriculture in 1998 had made a proposal to enact regulations on GR access in Taiwan. See also Kuo, supra note, at 39.

[105] Kuo, supra note, at 39. The Taiwanese laws relating to GR include National Park Law, Forest Law, Wild Animal Protection Law, Indigenous People Protection Law and Cultural Asset Preservation etc.

[106] Kuo, supra note, at 39.

[107] Id.

[108] The proceeding of the meetings is available at <http://seed.agron.ntu.edu.tw>.

[109] The GR draft law, Art. 7.

[110] Id. Art. 2. The Council may consult with other organs when necessary. See id. Art. 12.

[111] Id. Art. 7.

In general, the draft distinguishes academic bio-exploration from those activities conducted for commercial purpose. It adopts a relatively open policy towards the former, aiming at facilitating GR access process. As a result, the ABS requirement is exempted for academic applicants.[112] By contrast, any activity involving commercialization must fulfill the requirement.[113] With respect to the PIC, the draft favors the practice of multiple consent to the extent that a GR access project shall obtain the PIC from the following stakeholders:

1. The *competent body* of the public land where the exercise of a bioprospecting project occurs in public land;
2. The *indigenous people* in accordance with Indigenous People Basic Law and relevant regulations where access occurs on indigenous territory where the exercise of a bioprospecting project occurs on indigenous people land;
3. The *owner* where the exercise of a bioprospecting project occurs on *private land*.[114]

The denial of consent by the above interested parties shall constitute a condition in rejecting the access application.[115]

Taiwan's approach to PIC is similar to the Philippines and Brazil. But, it remains premature to say whether an anticommon problem would occur partly because the law is still in drafting stage. The anticommon at least would not happen to academic bio-research as the draft takes a loose and open policy upon it. It is of course fair to treat pure research and commercial access differently in term of the process of application. But, the author is skeptical to the policy that omits the PIC obligation for the former. As the PIC is to preserve the autonomy of stakeholders in participation and decision-making, their right to give consent should not be deprived even in the event of pure scientific research. It may be suggested that PIC should be maintained in the case. To avoid unnecessary burden imposed on academic applicants, the draft may consider allow the competent agency to participate the PIC process of this kind or to mediate the disagreement between applicants and those interested parties.

To ensure relevant stakeholders to have a better and reasonable judgment on the grant of consent, it is also proposed that the executive rule of the law should stipulate detailed regulations designed to supply resources providers sufficient information and to assist them in making the decision.

V. Conclusion

As indicated above, there remains a strong voice against international or national trend of delegating national government the power for full control on GR access. Of course, the consolidation of decision-making mechanism upon national authority could be problematic and creates some unsatisfactory results. Nevertheless, as Jeffery observes:

> National states will continue to play a pivotal role with respect to the development of any international legal framework regulating the access and use of genetic resources doe to the fact that it is the States, which retain both sovereignty and responsibility for conserving biodiversity within their jurisdiction. It is primarily for this reason that the implementation of the CBD has devolved upon that nation states and their sovereignty over these resources will necessarily determine the effectiveness of any access and benefitsharing arrangements including the enforcement aspects associated with these arrangements.[116]

Thus, the imminent question faced with the international community is how to ensure transparency for GR management and hold each national authority accountable in regulating bio-prospecting under their jurisdiction.

It was certainly a wise political decision to incorporate PIC in the CBD mandate on accessing to GR. But, the good provision alone cannot guarantee a better implementation and practice that may be in conformity with the objective of the CBD requiring a fair and equitable access regime. In contrast to the idea of informed consent in medical treatment, the PIC in the context of GR access regime appears more complicated and involves differential stakeholders whose consent should be respected and relevant in the final access permission. It is also suggested that due to its dynamic nature, the PIC process cannot be considered successful unless

[112] Id. Art. 8, para. 2.
[113] Id. Art. 8, para. 1.
[114] See Id. Art. 27.
[115] Id. Art. 22 (4).
[116] Jeffery, supra note, at 791-92.

the will of every stakeholders have been fully and squarely respected.

National legal arrangements and practices reviewed above indicate the discrepancy on PIC. Of course, it is not the intention of the CBD to unify the national practice of PIC, and State should be allowed to maintain discretion regarding the detailed operation of a PIC nationally. Although national government remains the eventual PIC granter, it is by no means the intention of the CBD to allow State authority to monopoly the PIC of which spirit should take into account the interests of parties whose life would be affected by bio-prospecting. It thus seems desirable and essential for the international institution, CBD mainly, in formulizing fair and effective supervision mechanism to assure the national implementation of PIC would be in conformity with the aims and objectives of the CBD.

Taiwan has started to establish GR regulations and already finished a preliminary draft. In terms of PIC, more efforts still need to make in order to strike a proper balance between the preservation of stakeholders' right to participate in one hand and the avoidance of unreasonable and ineffective PIC process on the other. It thus remains to be seen whether the law is a good work that may benefit every party.