

IUCN Study

Analysis of Claims of ‘Unauthorized Access and Misappropriation of Genetic Resources and Associated Traditional Knowledge’*

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9.1 Introduction and Background

The lack of widespread and effective implementation of access and benefit sharing (or ABS), despite its role as the third objective³²⁰ of the Convention presents an important challenge to the CBD COP. Within the past five years, efforts to address this challenge have occupied an ever-increasing amount of the time and resources of the SCBD, COP, Parties and observers. The impetus of this increase arises from two sources:

- The importance of the ABS objective; and
- The need to implement numerous firm commitments in the CBD relating to ABS.³²¹

The matrix of policy decisions and practical implementation mechanisms needed in order to enable and foster the creation of a functional ABS regime is recognized to be one of the most complex and demanding elements that remains in order to implement the Convention. In its seventh meeting, the CBD-COP identified a number of important issues for further study, as a primary step in addressing that implementation challenge. One of the specific studies required in that decision is ‘further analysis... of the extent and level of unauthorized access and misappropriation³²² of genetic resources and associated traditional knowledge.’³²³ This report provides the results of the first phase of inquiry into this issue.

9.1.1 Objective of this study

Examination of the extent and level of misappropriation of genetic resources (GR) is essential both:

- To clarify the nature and potential value of those resources; and
- To provide a clearer understanding of some of the contractual, implementation and enforcement obstacles that currently inhibit development and full functioning of the ABS system.

As explained in the next section, a comprehensive survey resulting in a quantifiable analysis of the extent and level of misappropriation is simply not possible. Consequently, this report does not attempt such an inquiry, but reflects an examination of the extent and level of *claims* of misappropriation, and the various ways in which they are asserted. It will not come to any conclusion regarding whether any claim described herein represents an actual example of misappropriation.

9.1.2 Methodology of this study

It is probably impossible to undertake a comprehensive, quantifiable analysis of ‘the extent and level of unauthorized access and misappropriation of genetic resources and associated traditional knowledge,’ because such an analysis would require the researcher to come to a conclusion about each controversial situation, deciding whether or not it constitutes an actual misappropriation or unauthorized access. Only a court can make such a finding, and many courts, when faced with such questions choose to decide the case on the basis of other issues, without deciding the ‘misappropriation’ point.³²⁴

To provide maximum information relating to the underlying objective of supporting the development of the ABS regime, this paper has researched and addresses claims of misappropriation, rather than being limited to those areas in which a finding of misappropriation has been made. It examines both formal and informal claims, and considers the various allegations and differences in interpretation that are the primary sources from which claims arise, rather than focusing solely on legal claims and the specific points of law on which they have been asserted. In other words, it focuses on claims themselves rather than on giving opinions regarding whether the claims will be upheld. These basic decisions are explained in this section, followed by a short description of the methodology for the collection of information concerning claims of misappropriation, and a description of follow-up research already being undertaken.

In this study, however, the author has been restricted by the lack of commonly accepted terminology for discussion of critical concepts.³²⁵ Given the imprecision and controversial nature of these definitional questions, the author has made no attempt to identify and use specific definitions of the term ‘misappropriation of genetic resources,’ ‘unauthorized access to genetic resources’ or any other term that might be used to describe ABS violations. While limiting the immediate conclusions and recommendations of the study (which are all conditional on the parties agreeing on the meaning of ABS and its key legal elements), this choice has somewhat broadened the discussions of various events and claims, many of which would not be considered to be a part of ABS under the definitional presumptions used by some parties and users. This article has not considered claims of biopiracy that did not include a clear allegation that the user made scientific use of a species for some other purpose than the conventional purchase/sourcing of ingredients (which does not seem to involve genetic resources under any serious claim so far asserted). Feeling that it was not appropriate to choose one among the currently supported views of what ABS is, what genetic resources are and what activities constitute their utilization, the author has included a rather broad panoply of other claims, extending from patenting through middlemen to actual scientific

use.³²⁶ Accordingly, this paper considers all claims that are alleged to be related to unauthorized or inappropriate utilization of genetic resources, and offers discussions and distinctions among such claims.

9.1.2.1 Impact of perceived/claimed misappropriation

Although in formal legal analysis a claim or perception carries less weight than a judicial finding or final decision, in practical terms the impact of a claim of misappropriation, may often be of greater concern than that of actual misappropriation.

The weight given to formal legal processes is a function of the objective of legal analysis – the attempt to find all of the factual and legal factors (including legislation and prior court decisions) that tell the lawyer how his client's case should be argued or will be decided. For this purpose, only final decisions can be thought to indicate whether a defendant is liable or not. In addition, it is often only final formal decisions that can have a legal impact on how subsequent cases will be decided. When looking at the impact of law on normal commercial behavior, however, the situation is quite different. Perceptions and claims themselves very often have the same impact as a court's decision. The assertion or the threat of such a claim, whether in formal venues or through the media, can often delay and interfere with commercial and other utilization of genetic resources. In this respect, it often does not matter whether those claims are ultimately proven to be groundless – they will still have an impact on the transaction or ultimate utilization of the resource.

In terms of their effect on the functioning of national ABS systems then, the number and nature of claims of misappropriation or unauthorized access is at least as important as their validity and final decision. As noted below, the focus on claims enables this paper to concentrate on the impact of misappropriation, rather than looking simply at the merits of a few legal actions. Hence, the report provides input into the primary underlying question – how have misappropriation *and claims of misappropriation* affected national and private attempts to implement ABS procedures and objectives?

9.1.2.2 Claim evaluation v. standard legal analysis

In terms of its content, a standard legal analysis will not address the ultimate needs for which this study is conducted. Typically, a legal analysis focuses on (i) decisions, (ii) pending cases, (iii) formally asserted claims, and (iv) informal claims and negotiations, in that order of priority. This approach is based on the manner in which legal issues are addressed in society, and the fact that formal cases carry greater weight in judicial decisions than pending cases, while pending cases carry more weight than formal claims, and so on.

Standard legal analyses also generally focus on analyzing the particular legal points ('causes of action') on which the case or claim is based, to determine their validity and usefulness, and to clarify the exact factors within each cause of action that must be proven in order for the plaintiff to succeed. These decision-making processes form the *legal analysis*, undertaken by parties, lawyers, judges and/or mediators to enable the development of a legal strategy, to prepare the final decision, or to decide whether it will be better to negotiate with a claimant or allow him to bring suit. In each case, these particular causes of action to be asserted are selected based on the legal strategy of the parties asserting the case. They are chosen on the basis of the lawyers' estimation of the chance of success, and rely particularly on matters such

as the specific text of national laws, the wording of relevant decisions in other cases, known preferences of the assigned judge, and other matters.

The current paper is not intended to provide an estimate of the strength of a legal case in a particular factual situation for purposes of a future lawsuit. Rather it has the very different objective of informing the Ad-hoc Open-ended Working Group on ABS (AHWG-ABS) regarding the extent to which misappropriation poses a problem for the functioning of the ABS regime. As such, the paper is addressed to the ‘meta’ level of legal issues – focusing on the disagreements and uncertainties that underlay claims of misappropriation/unauthorized access. By understanding this, the Parties can better understand the particular gaps that exist in the current ABS regime, and the areas in which clearer principles and provisions are needed to eliminate uncertainties and minimize claims.

9.1.2.3 Design of this analysis

This paper presents the following information:

- An overview of the information provided and collected, and the approach taken to its collection;
- An analytical summary of the information collected, at three levels of analysis:
 - Overall information regarding the claims and cases studied;
 - Categorical analysis of various types of claims; and
 - Specific information on particular claims or sets of claims, focusing on the following specific questions:
 - How did the claim arise, and especially, how did the claimant come to know of it?
 - What kinds of uses were involved?
 - At what stage in the process was the claim first asserted?
 - What defences or other statements have been made opposing the claim?
 - What is the current status (or outcome) of the situation?
- A substantive summary of the information collected, addressed to the question of their relationship to and impact on ABS implementation.

This initial analysis has been limited to material: compiled from the internet and other available public descriptions of cases and claims; obtained through direct connections and telephone inquiries; and obtained via initial inquiries through some of IUCN's regional offices.

9.2 Information sample

This section provides an overview of the methods used to gather information on cases and claims analyzed in this report, including both the primary information-gathering processes (material available in websites, public filings and other publicly available sources) and secondary processes, designed to obtain information through other sources.

9.2.1 Information submitted to SCBD and other public sources

The initial data for this study was compiled by the CBD Secretariat, using publicly available resources, including primarily the internet. This information was supplemented by additional

direct research through a variety of public sources of information. Although extensive research resulted in numerous discussions of claimed misappropriation, the vast majority of these documents were eventually found to refer to the same 20–30 formally filed or widely publicized claims (included in the list in [Table 1](#)).

While some of the information obtained in this study came from official records in the country in which a claim was filed (usually limited to patent actions), access to these records has been difficult, and usually depends on knowing significant information about the claim (including names of parties and specific courts or other bodies in which the claim was filed). Hence, it was necessary to initiate a study of less official records – newspapers and web-based, including websites of governmental agencies, NGOs, universities and commercial bodies. Often, these sources were able to provide significant information, but did not include the data necessary to locate official records of cases, patents, and other relevant information.

Hence, while it was possible to obtain information about the existence of controversies, it was generally difficult to obtain a systematic set of underlying facts to serve as a basis for comparative analysis.³²⁷ [Table 1](#) describes the current state of knowledge, with empty boxes indicating those points on which it was not possible to obtain reliable information.

Table 1. Public claims identified (initial study)³²⁸

Genetic resource and other identifiers	Source countries	Type of claim	Current status
Ayahuasca Banisteriopsis Caapi	Ecuador	Formal case/claim	No longer active
Basmati	India	Formal case/claim	No longer active
Cunani and Tipir	Brazil	Formal case/claim	Closed
Endod or Soapberry Phytolacca dodecandra	Ethiopia	Public outcry	No longer active
Yellow Bean (product ‘Enola bean’)	Mexico	Formal case/claim	Pending
Tricolor Frog	Ecuador	Threatened case	Unresolved
Kalahari Hoodia Hoodia gordonii	Namibia, RSA	Threatened case	In negotiations
Extremophiles	Kenya	Threatened case	In negotiations
Maca Lepidium meyenii	Peru	Public outcry	
Nap Hal (wheat variety used in chapatis)	India	Formal case/claim	Decided 2004
Neem Tree	India	Formal case/claim	Decided 2002
Pozol	Mexico	Public disclosure at minimum. Precise data on nature/status of claim not yet discovered.	
Selva Viva: General claims re	Brazil	Formal case/claim	Decided

prospecting

Swartzia Madagascariensis	Zimbabwe	Demand	No longer active
Turmeric Curcuma longa	India	Formal case/claim	Decided 1998
Acai Euterpe precatoria	Amazon region	Public disclosure at minimum. Precise data on nature/status of claim not yet discovered.	
Traditional plant medicines (AMMA corp.)	Peru	Public disclosure	
J'oublie Berry (patented product name 'Brazzein')	West Africa (Gabon)	Public disclosure	
Philippine Snail Conus magnus	Philippines	Regulatory challenge	
Copaiba Copaifera sp.	Amazon region	Demand	
Cupuacu Theobroma grandiflorum	Amazon region	Formal claim/case	
Jamun Syzygium cuminii, Karela Momordica charantia Lin and Brinjal Solanum melongena L	India	Public disclosure	
Bitter Melon	Thailand	Public disclosure +?	
Hom Mali (Jasmine Rice)	Thailand	Demand	
Kemukus Piper cubeba and Sambiloto Andrographis panicurata	Indonesia	Public disclosure	
General seeds collection (Millennium Seed Bank)	Kenya	Regulatory challenge	Resolved
Nuna Bean	Andean region	Public disclosure	
Kaw Krew (compound 'Pueraria mirifica')	Thailand	Public outcry	
Plao-Noi	Thailand	Public disclosure	
Quinoa	Andean region	Public outcry	User rights abandoned
Snake Gourd	China	Public disclosure +?	
Teff	Ethiopia and Eritrea	Public disclosure +?	
General prospecting for species and compounds	Venezuela – Yanomami land	Public outcry and possible demand	
'Junk' DNA from all living species	All	Public outcry against patent (on one hand), and patent defense actions (on the other)	
Other: Cat's Claw, Sangre de	Amazon	Public disclosure	

Drago, Quebra Pedras and Wormseed	region	
Other: tamarind, haldi, ginger, anar, pepper, amla	India	Public disclosure

The initial process of obtaining information illustrates a more general problem relating to ABS – the manner in which information on ABS issues and GR use can be found. The basic mechanism for finding this information was an iterative search process. The first step was to search generic key words, such as ‘genetic resources’ and ‘biopiracy’ through public search engines (Google, Altavista, Yahoo) as well as closed legal and official databases (governmental sites containing, for example, patent information and national laws and cases). This search produced a list of cases, including information on the names of species and varieties, products, and actors. The second step is to run a series of specific searches of the terms and names discovered in step 1. The third step was to evaluate the information on each case, to determine whether it involved a claim of misappropriation of genetic resources (thereby belonging in this study) as opposed to a claim based on utilization of biological resources, non-genetic-related TK or other matters.

However, the limitations of this approach become obvious rather quickly. For example, this multi-level iterative process is very long and can be expensive when it involves closed or fee-based databases. Consequently, it was not possible to search all terms discerned by step1³²⁹ in the databases available to the authors. In addition, it was not possible to use these tools to uncover information on less public claims, unless they used a particular suite of critical terms.³³⁰

The need to base searches on a comprehensive list of key terms, however, is the most critical limitation. The only way to find relevant public filings electronically is to search for specific words and concepts. It is nearly always possible, however, to complete relevant filings without ever using such terms. Applicants are rapidly learning to take special care to avoid ‘hot button’ words (‘genetic resources,’ ‘traditional’) or any reference to the location from which the components were derived. The required level of detail can be satisfied by naming the specific species, or even less searchably, by including chemical formulas and other scientific descriptions, or developing product names for identified compounds and sequences. It is virtually impossible to develop a key-term list that includes all scientific and common names of a country's indigenous or endemic species as well as all of the chemical compounds and other scientific descriptions of their usable characteristics, and virtually impossible to search them all in all relevant databases.³³¹ In other words, if you do not have specific information about a particular claim of misappropriation, it may not be possible to find it.

While problematic in terms of the research for this study, this report's underlying task is to demonstrate areas for development, rather than to bemoan the lack of appropriate tools. To that end, the fact that modern research methods provide only a random chance of finding users (unless they disclose themselves) is worth noting. It suggests that the only effective way to approach the problem is to form the ABS regime in a way that creates significant and worthwhile incentives for users to self-report and to comply with ABS requirements. Presumably, the current negotiations can address this need as a part of their mandate to make the ABS regime functional and effective.

The third step in the analysis – evaluation of each claim to determine whether it alleges misappropriation of genetic resources – was only minimally possible given the lack of reliable sources of complete information.³³² This element has not been completely possible at present funding levels. Many of the identified claims (especially those that were informally asserted in the public media) simply disclose the existence of a patent or patent application which names or refers to a particular country, species or remedy. Without review of the patent documents and additional information about the country, species or remedy, one cannot determine whether any formal patent action is warranted. Moreover, it is necessary to fully analyze this information, in order to identify the nature of the claim and whether it actually addresses any CBD-related issues (GR use or GR-related traditional knowledge (GRTK), misappropriation of genetic resources, invalid or non-existent rights of access, etc.) rather than more conventional claims based on existing legislation and legal theories.

9.2.2 Data obtained through secondary research

Beyond the use of advanced electronic tools, however, a further information-gathering phase of this analysis was carried out by the author of this paper using telephone, e-mail and other direct contacts. This work, too, is ongoing, as additional sources and issues have been identified throughout the course of this study.

The main objective of this process has been the development of information regarding non-public claims. For a variety of reasons, relatively little information regarding such claims is available, except through direct contact with individuals from all sides involved in those activities. This process also acquired further data on the various publicized cases and claims discerned through the electronic search, providing significant additional information regarding the facts that gave rise to the claim and the manner in which they became known.

From the outset, this component of the study demonstrated several key obstacles that frequently arise in ABS research and development – facts and factors that would tend to prevent disclosure. While the users and providers (both national and private) have stated their collective desire to maximize the information available to AHWG-ABS and to the COP, these desires often conflict with more specific national, institutional or commercial objectives. Few motivations induce companies, governments or other stakeholders to provide information, while several strong disincentives obstruct disclosure, including the following:

- *Providers:* Contractual limits of disclosure. Many ABS agreements are marked as “Confidential” or contain specific provisions limiting the right of one or both parties to disclose the terms of the document.³³³ The legal effect of these contractual provisions requiring confidentiality is often limited and may not be entirely clear. However, the primary objective of confidentiality of the contract's contents is often supported by the courts. Hence, public disclosure of the agreement's terms to a public body for purposes not directly connected with the execution of the document may be an actionable violation of that agreement.
- *Users:* Desire to avoid disclosures leading to negative perceptions. Companies and countries usually prefer that biopiracy claims and other claims of irregularities should not be publicly asserted, even where the company is confident that its actions are equitable and legally defensible. Even if its position has been formally upheld by the courts or other deciding bodies, public discussion of the issue is undesirable.³³⁴
- *Users and providers:* Desire to avoid potential libel or other court action.³³⁵ There is a further concern relating to unproven claims of misappropriation – the possibility that,

by describing a claim, the party providing the report will be open to accusations of libel, slander or other damage. For example, a public claim that a company does not have appropriate title to valuable assets may cause a disruption of that company's commercial opportunities. If the claim is later ruled to be unfounded, these lost commercial opportunities could become the basis of a lawsuit. Hence, it may be preferable to avoid making such statements until they have been fully researched and proven, and especially until all options for negotiated settlement have been exhausted.

- *Providers:* Desire to protect bargaining position. This can be a strong disincentive, applicable to a significant number of claims relating to possible misappropriation. As discussed in Part III of this paper, the promise of confidentiality can be a major incentive that brings opposing parties to the table in benefit-sharing negotiations.

To address these challenges, this analysis has been conducted by an independent organization (IUCN) which can receive information with the promise of confidentiality. Approximately 70 people were contacted seeking information about claims of misappropriation. Nearly 45 of these persons have replied with some level of substantive information. Statistically, this level of response indicates that the inquiries were well targeted and that respondents had an appropriate level of confidence in the confidentiality of their responses.³³⁶ (All responses received in this portion of the analysis will be kept confidential for purposes of this initial analysis. In subsequent processes, efforts will be made to find a non-biasing way to provide the names of those who specifically allow such disclosure). The study has found that there is a wealth of relevant information available, both regarding claims and the manner in which they have been addressed and resolved.

Table 2. Participants in confidential interviews (to date)

Government	Industry	NGOs and indigenous groups	Research facilities	Other ³³⁷
40%	21%	19%	14%	6%

In general, it was less easy to compile the responses to the secondary investigation in tabular form than the public cases identified in [Table 1](#). Interviews tended to focus on categories of claims, and where specific information was provided it was often given with strong restrictions relating to confidentiality. Information received is not described in a way that will violate those restrictions, however, it is fully integrated into the discussions in [sections 9.3](#) and [9.4](#) of this paper. The following table describes the primary information obtained through the secondary information-gathering process:

Table 3. Less public and non-public claims identified

Type of claim %	Respondents ³³⁸
Formal lawsuit	13
Administrative appeal	20
Denial or dismissal of ABS or other permit application	27
Opposition in ABS processes	47
Claim of other legal violations in obtaining or using specimens	16
Allegations asserted in other ways, without formal complaint or process	73

Similar to the public process, most of these interviews indicated a very high level of non-formal actions and claims (parallel to those referred to in [Table 1](#) as ‘Public disclosure’ and ‘Public outcry’), and only a very small number referred to formal legal action (generally focusing on some of the actions described in [Table 1](#)). However, the private interviews discerned a high level of administrative action – spanning a range from formal participation in (or objection to) ABS negotiations to public statements of disapproval expressed at local or national level, including requests for government action against purported misappropriation.

9.3 Nature, source and objectives regarding claims

This section presents and analyzes the underlying information regarding the actual claims identified through this study. It provides a general overview of the nature of claims described in [section 9.2](#). Although not analyzing the specific legal theories or facts alleged in the various claims, this section considers five primary elements that are of particular importance to the analysis of the nature of claims and responses to claims, as well as the underlying motivations that drive them:

- Who is making the claims and against whom;
- The manner in which the claimant became aware of the underlying facts;
- The nature of the injury or loss that prompted the claimant to assert a claim;
- The apparent objectives underlying the claim; and
- The deciding body or governing principles on which the claim is based.

These factors provide some useful information about the ways in which claims arise, and the reasons they are asserted, which will be considered in more depth in [section 9.4](#).

This discussion will not delve deeply into the actual uses or other underlying facts, except as illustrations, and/or to note that in a majority of the cases and claims studied for this paper, the value of the rights being challenged was generally unknown and incapable of estimation at the time the claim was asserted. In several cases, claims have been asserted and publicized well before any samples or information were collected, while in others the first assertion was based on information found in public advertisements and marketing materials for an internationally marketed GR-based product.

9.3.1 The parties (claimant and subject of the claim)

As a preliminary matter, it is useful to consider the categories of entities and individuals involved in claims of misappropriation of genetic resources. In general, claimants fall into three categories:

- Directly affected individuals/communities/stakeholder groups;
- NGOs; and
- Governments.

The claims are typically made against some combination of the following:

- A commercial entity or developer of commercial uses;
- A source-country government issuing permission;
- The original collector; or
- A middleman or information peddler.

To date, although claims are often brought seeking rescission of decisions made by the user country's governmental bodies, few claims have been made directly against any user country calling on it to implement Article 15 or equitable principles concerning genetic resources.

Private and NGO claimants

In the overwhelming number of claims, regardless of who brings or promotes the claim initially, NGOs have taken a major role in providing legal services and publicizing claims through the news media, internet and other forums ([Table 1](#)). For example, in about 88% of the cases identified in [Table 1](#), NGOs had a very early role in publicizing the claim. All of the eight formal legal actions reported in that table involved action by or with assistance from NGOs in researching and presenting the claim.

Governments as claimants or defendants

One key factor in the manner in which claims are brought relates to whether governmental entities (or any group of them) are claimants or defendants. Of the public claims listed in [Table 1](#), only four included any direct action calls against government for failure to complete appropriate ABS procedures, or alleging other particular errors in those procedures. These claims focused on public notice questions and response to public objections (asserted during or after the government/user negotiation processes). In only one of the reviewed claims, ³³⁹ has a formal allegation been made that the benefits received from the user were not distributed appropriately.

The confidential interviews disclosed a much higher level of claims against government arising in the form of regulatory challenges within the ABS agreement process. More than half of the government representatives responding, and all industry interviewees stated that ABS-related processes should always be expected to raise some public objections, potentially leading to protracted discussions. As one government representative stated, ‘in some people's minds, any ABS agreement is biopiracy.’

Where the source-country government is not being complained against, however, it is often either a claimant or supporter of the claim. Most government representatives interviewed indicated a strong preference for informal processes and negotiations, where possible. In several cases, however, the government took a primary role in negotiations with the user, often working in coordination with NGOs, indigenous groups and others.

CGIAR international agricultural research centers

Research indicates another potential category of claimants – the CGIAR Centers. Their mandate is to ‘collect, characterize and conserve agricultural genetic resources’ as part of a larger mandate to ‘mobilize agricultural science to reduce poverty, foster human well-being, promote agricultural growth and protect the environment’ through:

- Promotion of sustainable production;
- Enhancement of national agricultural research systems;
- Germplasm improvement;
- Germplasm collection; and
- Policy. ³⁴⁰

The CGIAR clearly views its mandate as providing public resources for publicly beneficial purposes, stating that it ‘generates global public goods that are available to all.’ As such it strictly limits the ability of any recipient of material from any of its International Agricultural Research Centres to patent or otherwise restrict the use of the variety involved.

Much of the seed transfer system through the international agricultural research centers (IARCs) that are aligned under the CGIAR has been carried on under Material Transfer Agreements, which are contracts in form, but often evaluated under general CGIAR experience rather than individual contract law of particular countries.³⁴¹ These evaluations generally turn on existing law relating to the hybridization and other development of agricultural varieties, suggesting that they may be matters of conventional uses.

In general, based on a very limited set of interviews, it appears that the IARCs are able to resolve violations of material transfer agreements contractually, although no information has yet been provided regarding the frequency with which such resolution is needed. The IARCs have been somewhat directly involved in at least three of the publicized cases reviewed for this paper. For example, in one instance, a CGIAR centre resorted to asserting legal or public claims against a user (the ‘Yellow Bean’ case). In another case (Acai), local claimants have publicly sought involvement and policy development by the relevant CGIAR centre, and a higher level of ongoing responsibility controlling and overseeing intellectual property claims. Regarding jasmine rice, the user claims a CGIAR centre as the source of his original samples of the variety. In this connection, it should be noted that CGIAR has a Central Advisory Service (CAS) on intellectual property issues, which examines these matters.³⁴²

Claims against users, researchers, collectors and middlemen

Most commonly, claims have been made against the commercial user of GR and/or the applicant or holder of a patent referring to natural or traditional varieties, traditional remedies, or traditional sources of information. Only four of the specifically listed public claims do not include a commercial user within the claim. In some well publicized instances, claims have been made against persons who marketed knowledge or samples to other companies or commercial organizations. The claims were based on allegations that a collector or cataloger had failed to disclose his contract or other intent to share genetic resources, samples and knowledge with commercial entities after collection. These claims represent the only criminal penalties or proceedings identified in the research to date.

9.3.2 Claim mechanisms

As with all legal and policy-related issues, claims relating to misappropriation of genetic resources typically use one or more of the following eight mechanisms:

- *Lawsuits and formal legal processes:* In the context of this study, relatively few claims utilized formal legal process. Most of these claims were filed in national patent agencies, either opposing patent issuance or calling for revocation of an existing patent.
- *Administrative citation, penalty or license revocation:* In a few cases, direct administrative action in the form of a formal citation or penalty or the revocation of a license or other permission to collect or utilize specimens have been undertaken. In some cases, these administrative processes are a required prerequisite to litigation

(i.e., the government must ‘exhaust administrative remedies’ before a case may go to court).

- *Objections filed in administrative processes:* A number of claims have been filed in administrative processes by members of the public, including NGOs, indigenous groups and others.³⁴³ In general, these claims arise when an applicant sought a non-ABS permit or agreement (permit to conduct research in protected areas, CITES export permit, etc.) and claimants challenged the process as an attempt to evade the operation of ABS law.
- *Administrative objections to the issuance of ABS or other permissions:* In a number of instances, public objections and other claims have been asserted after an ABS agreement or other permit or license has been obtained, seeking its rescission. These objections generally claim that the issuing process was invalid, and that due to this invalidity the resulting permit enables a misappropriation of genetic resources.
- *Formal request on government to take action against a purported misappropriation:* In a few cases, members of the public, including NGOs and indigenous groups, have issued formal requests to government agencies calling for action against a user for violation of ABS requirements. This kind of request may sometimes be required or recommended as a preliminary step before bringing a lawsuit against the government agency.
- *Public disclosure or outcry:* Many of the claims use completely informal mechanisms – public media and awareness tools. While the full breadth of this kind of opposition has not been studied, it is clearly a major mechanism for raising ABS claims at present.
- *Direct request or demand on user:* Another informal mechanism (primarily described in interviews) is direct contact with the user. This contact usually takes the form of a request or demand that the user can alleviate the potential claim by ceasing certain activities, or agreeing to meet benefit-sharing obligations.³⁴⁴
- *Direct request or demand on the government with jurisdiction over the user:* Another mechanism, which has been reported rather infrequently, is direct contact with the user's government, asking it to take action to ensure that the user meets his benefit-sharing obligations under the CBD. This mechanism has been considered by source countries and other claimants, when addressing user countries that have not adopted ‘legislative, administrative or policy measures... with the aim of sharing in a fair and equitable way ... the benefits arising from the commercial and other utilization of genetic resources.’³⁴⁵

As further noted below, the selection and use of these mechanisms is strongly affected by existing uncertainties relating to ABS law and compliance.

9.3.3 Claims involving traditional knowledge

One critical concern in this analysis relates to claims relating to traditional knowledge. As noted in many documents addressing a wide variety of aspects of CBD practice, the concept of traditional knowledge, and the rights of indigenous people and communities embodying traditional lifestyles are much more extensive than the entire scope of the Convention, and even within the CBD are discussed in contexts other than ABS. Typically, however, ABS discussions have recognized that a subset of TK issues – those involving GRTK – appear to be included within Article 15.

The concept of GRTK, however, remains somewhat undefined. Hence, while a great many cases and claims involving traditional knowledge issues have been discerned in this analysis, it has been difficult to determine which of them actually involve access to genetic resources.

In cases of doubt, this analysis has generally erred on the side of greater inclusion. Where a claim focuses solely on the use or patenting of biological material or existing traditional remedies, such claims have been excluded from this study, based on the belief that ABS is not intended to address normal commercial markets in biological materials. Where it was not clear, however, whether a claim also included the use of traditional information for purposes of genetic manipulation, utilization/replication of a genetic sequence, or replication of a biochemical formula, the claim was included in this study.

9.3.4 Discovery of the facts underlying the claim

In general, there have been only a small number of potential avenues by which the claimants discovered the use or activity that formed the basis of their claim. Many of the public claims (and some of the less public claims) have arisen where a member of an affected group or an NGO has happened to find references to a species, variety, remedy, country, geographic area, cultural group, or particular compound in:

- Patent databases;
- Corporate (public) annual filings and reports; or
- Notices of royalties.

Claims based on these discoveries have often taken the form of ‘public outcry’ against the patent or product use. In some cases, after discussion with relevant government offices (to determine whether a permit or other approval has been given), the discovery has been the basis for direct initiation of negotiations with the user. Several government officials, however, reported first hearing of claims when NGOs publicized them.

It should be noted, however, that these discovery mechanisms are very general in content. Often, the claimant is unable to view or review the relevant documents (patent or patent application), or to obtain complete information regarding the relevant facts from these sources. As a consequence, in the context of patents, for example, it may not yet be possible to know whether a patent is actually invalid or involves any actual misappropriation or not.

Other modes of discovery have included statements in product packaging and other promotional materials, local advertizements seeking samples or sample collectors, and telephone calls from interviewers asking for details about a reported agreement. At present, no information has been collected (in interviews or elsewhere) in which discovery of facts suggesting misappropriation has occurred through the interception of material in customs, or through the apprehension of collectors in the field. This may not be unexpected, given that it is not possible to determine objectively whether biological material (in transit or being collected) was taken for the utilization of genetic resources, or simply for (legally permissible) conventional sale of biological material.

In some cases, the discovery of the potential claim occurred through required public notices given under national ABS legislation, including announcements of domestic requirements for public participation. This fact was cited by all industrial sources and most governmental

sources, as an indicator that current uncertainties regarding ABS concepts have resulted in a high level of targeting against compliant industries.

9.3.5 Kinds of harm/loss alleged

Although the legal theory or argument alleged in each claim is not precisely relevant to this study, it is important to consider the nature of the motivating force behind them – i.e., the underlying injury, damage, harm, expectation or loss that prompts claimants to take action. The nature of the primary harm perceived by the claimant, and the nature of the remedy expected, are key issues determining the level and nature of claims.

Table 4. Nature of loss alleged

General harm claimed	% of respondents and assessed situations
Direct harm to commercial/livelihood interests	36
Potential harm to commercial/livelihood interests and expectations	73
Inequitable actions – gaining a benefit from GR obtained, without sharing with source, pursuant to Art. 15 and/or national law and other legal principles	96
Failure to comply with primary ABS requirements	83
Unpermitted publishing or transfer of genetic or biochemical information	68
Damages or lack of rights in specimen collection	11

In general, this study found that there were six categories of loss or damage that were asserted by those claiming that a misappropriation, unauthorized use or similar action³⁴⁶ had occurred.

In many of the interviews and situations assessed, the claimants alleged more than one type of loss or harm, although typically one underlying injury or concern was predominant.

In connection with this discussion, it is important to note that most public claims ([Annex 1](#)) include many different allegations, often including more than one of these elements. Thus, for example, nearly all patent-based claims also include specific allegations of genetic resource use without ABS compliance, unpermitted transfer of GR rights, and the failure to share benefits. This overlap is the predominant approach, so that one can assume that all claims allege more than one type of harm, and most allege at least four of those listed above.

9.3.5.1 Direct harm to commercial/livelihood interests

By far the most compelling claims arise where the user has directly taken or caused a diminution in the rights of farmers and other persons in the source country to use and market varieties and rights which form the basis of their existing livelihoods. A few powerful examples of this involve a user who patented an agricultural variety that is virtually identical to a traditional variety being cultivated and marketed by farmers and **others in the source country**.³⁴⁷ In one case (the Yellow Bean case), the patent holder then claimed a royalty from traditional farmers. Similar situations have arisen, in which the patent application was

challenged before any attempt had yet been made to **assess farmers using the traditional product, or otherwise limit their rights.**³⁴⁸ In general, these cases have focused on the patent of a traditional variety (or conventional variant on such a variety), rather than on the creation of new varieties based on the **traditional variety using genetic (non-conventional) technologies.**

9.3.5.2 Potential harm to commercial/livelihood interests and expectations

A large number of the publicized claims, as well as many of the claims discussed with individual contacts related to the impact of unauthorized use on the future commercial interests and expectations of a source country or a community or group within it. Many, but not all, of these cases involve the use of GRTK.³⁴⁹ For the purposes of this paper, GRTK includes those instances in which knowledge of a particular traditional use or remedy provided a clue for researchers who then isolated and used genetic or biochemical information from one or subspecies/variety used.³⁵⁰

In this category, a large number of claims have been asserted, primarily through the public media (by ‘public outcry’), but also some patent-related actions. These claims generally focus on traditional remedies and other products. The harm involved was generally described in two ways:

- Equity-based harm – claiming that some organization or individual was obtaining a commercial benefit from information or genetic resources within the sovereign rights or other authority of a country or indigenous community (further discussed below).
- Harm to future interests – stating that the patent will prevent the source group (holder of the traditional knowledge) or country (holder of sovereign rights over the genetic resources) from developing knowledge, remedies or resources and marketing them.

As with the prior discussion, this denial is made more serious by the fact that under the application of internationally accepted principles of patent law, the users and traditional holders within the source country could not patent the product themselves (because one can only patent a new innovation that is not generally known). In light of globalization, however, patenting anywhere essentially denies the source/origin countries, communities and individuals the ability to develop and obtain commercial value from these products of their biological and genetic material and of their cultural and traditional knowledge.

Instances of this kind of harm are identified in nearly all of the public claims, which have overwhelmingly focused on patents, both as a basis of discovery and as the mode by which particular harm was alleged. Of the public claims identified in [Table 1](#), only nine – specifically the Hoodia, Kenyan extremophiles, Selva Viva, Amma Corporation, Millennium Seed Bank, Philippine Coral, Plao-Noi, Yanomami Land and Coco-de-mer – did not appear to arise out of a patent. The claims arose in a variety of ways. In three (Kenyan extremophiles, Hoodia, coco-de-mer), the claim arose from discovery that a product had been developed. Four of these cases (Amma Corporation, Philippine Coral, Selva Viva and Yanomami) alleged intentional efforts to obtain information or access without full disclosure of the intent to sell the information/genetic material obtained, or to use it commercially. One case, the Millennium Seed Bank, arose out of the public knowledge of ongoing negotiations for the creation of a non-commercial collection. At least one of these (Amma Corporation) resulted in a criminal case, and at least one other (Philippine Coral) in the revocation of the

permit for sample collection. Only one other (Millennium Seed Bank) has since been resolved. The other claims are either still under negotiation or abandoned.

By contrast, most of the confidential interviews disclosed a much broader scope of claims, and indicated that there are many more claims relating to ABS violations which have nothing to do with patents granted or applied for. Thus, for example, a large number of claims appear to allege that the public consultation processes were incomplete, or that the public group giving consent (where required by law) was not authorized to take action on behalf of the community or stakeholder group in question. Challenges to the scope of the rights granted in an ABS permit, the agreed amount of benefits, and the manner in which they are to be distributed within the source country are also relatively common. In a number of cases, public concerns focused around the fear that users who receive some kind of permission (ABS or other) to collect specimens or catalog information will later use that information commercially without sharing benefits, unless they are legally prevented from doing so.

9.3.5.3 Inequitable actions – using GR without sharing the benefits

The harm involved in many misappropriation cases is one of expectation – that others should not be allowed to profit from the source country's resources and historic conservation of those resources without sharing those benefits equitably. This is a very different kind of harm, which goes to the heart of the ABS issue. These claims find their basis in a primary concept in common-law countries where they are referred to as 'equity' – the legal notion of fairness extending beyond the contents of contracts and the strict interpretation of contractual rights.

Box 1. Equity

For example, consider the situation in which Mr. Y gets permission from Mrs. X to pick roses from her garden to decorate his dinner table. After they are picked, Mr. Y enters the roses in a flower show where they win a prize.

The right given by Mrs. X may be both a kind of contract and a property right (the right to trespass on Mrs. X's property). Is Mr. Y's decision to use the roses in a different way a breach of contract? Principles of contract law would probably not decide this, because under contractual law there is no direct measurable harm to Mrs. X – she had agreed to give away the flowers, anyway, hence there is no damage to her.

Principles of equity, however, also apply. These principles provide a different result. Mr. Y has obtained a benefit from Mrs. X's excellent gardening and from her development or preservation of a unique variety. Even though Mrs. X would not enter the flower show herself, principles of equity would hold that Mr. Y must, at least, share the prize money, give her credit for development and cultivation of the roses, and recognize her ownership rights.

Most of the publicly asserted claims examined for this report, although mentioning these equity issues as a supporting point, have not sought equitable remedies (a share of benefits, or a promise to share them in future), but rather call for invalidation of patents or similar rights. Although not yet applied by any court, equity principles have been raised in non-public discussions and negotiations, and the use of GR without benefit sharing has often been the specific and primary basis for the claim.

Equitable principles have been most prominent in civil and criminal actions against middlemen and collectors. In several instances, the source country took action based on the (equitable) collector/middleman's obligation to disclose his intent to sell the information and samples for purposes of commercial development. Three such claims have been publicized, resulting in fines, rescission of permits, and (in one case) expulsion from the country.

More than 65% of the individuals interviewed had been involved in some ABS challenge based on fears that the collector would be able to transfer the material to a commercial user after the samples were removed from the country without any payment or even notice to the source country. These claims are based on equity issues.

9.3.5.4 Failure to comply with other primary ABS requirements

Misappropriation claims sometimes suggest that a particular user or applicant has not complied with the primary requirements of ABS law. These claims span a rather large spectrum from, at one end, allegations that the ABS-legal compliance was insufficient to comply with specific legal requirements,³⁵¹ to, at the other end, allegations that ABS obligations were completely ignored and no ABS agreement obtained. Records of administrative claims have been difficult to acquire, however. Interviews with individuals from governments, industry, academic/research institutions, NGOs and indigenous groups have provided informal descriptions of their experience with formal objections to ABS applications and permit processes, as well as other government permissions, such as CITES export permits and permits for research/cataloging and sample collection in protected areas.

The most basic allegation, of course, is that the user simply omitted any effort to obtain a right to utilize the genetic resources, so that his activities constitute a misappropriation of genetic resources or GRTK. In some instances, where an ABS agreement has been negotiated, flaws in the procedures (especially public participation and consent requirements under national law) have been asserted as bases for declaring that the agreement is invalid and activities under it are misappropriation. In other cases, the claim alleges that the government negotiators have not exercised due care in protecting the country's sovereign rights and property interests with regard to its genetic resources. In essence, these claims allege that the grant of access or other rights was illegal or represented a violation of government's obligations to obtain the maximum return on natural resources and sovereign properties.

In these cases, there was a significant difference between the claims mentioned by source-country governments and those by private individuals, NGOs and others. Governmentally asserted claims generally focus on the entire failure or refusal of a user to obtain or comply with ABS agreements. For governments generally, particular errors or omissions within such agreements are generally considered to be remediable problems except where the applicant intentionally made some misrepresentation. It should be noted that, apart from patent claims in which ABS omission is stated as a supplementary basis for the claim, there have been relatively few claims raised by source-country governments alleging ABS violations.

At the level of individual and NGO claims, however, a greater proportion appear to focus on governmental authority to issue permits, and more particularly on issues of specific compliance with national and/or sub-national law, including:

- Sufficiency of compliance with public participation requirements;

- Acceptability of financial provisions in agreements; and
- Distribution or arrangements for distribution of benefits at the sub-national level.

Approximately 33% of NGO representatives discussed such claims, and most of the government and industry representatives had experienced them at some level, however few of the public claims listed in [Table 1](#) were based on this kind of issue. Although persons asserting claims of this type generally desired publicity for their claim, they were rarely publicized widely (although sometimes receiving detailed coverage at the most local level), and have been difficult to locate through online or other research.

Many of these claims focused on users who did not believe that their activities utilized genetic resources. For example, the Millennium Seed Bank claims arose in the context of a governmental permit enabling the creation of a conservation collection, with no known intent to use the collected materials for any commercial purpose. Claims were based on an underlying concern that once the material was removed from the source country, that country would have no right or ability to maintain awareness of the transfer of the material and/or utilization of its genetic or biochemical information. Several similar claims involving collections, taxonomic surveys and comparable proposals were identified in individual interviews, in all of which the applicant did not request (and the government did not grant) any right to commercial use of the genetic resources.

9.3.5.5 Publishing or transferring information without a right to do so

A number of claims focused on the transfer of other rights, such as the right to engage in research, contracts for the collection of taxonomic data, or contracts for the development of specimen collections and herbariums. Although these arrangements do not specifically grant any right to utilize genetic resources, as conceived by Article 15, the contracts raised questions regarding the future use of the material and information obtained, after the contracting party had collected and removed the data or material from the country of origin.

Here also, the claims generally related to users who did not believe that their activities utilized genetic resources, such as the Millennium Seed Bank claims arose in the context of a governmental permit enabling the creation of a conservation collection, with no stated intent to utilise the collected materials for commercial purposes. Similar claims and comparable proposals were identified in individual interviews. In all of these cases, the applicant did not request (and the government did not grant) any right to commercial utilization of the genetic resources. The primary expressed motivation underlying the claims was the fact that after removal of the material, the source country would have neither the right or ability to maintain know of or monitor transfer of the material or its genetic/biochemical information.

These claims are fuelled by the existence of another category of allegations – transfer of biological material and research results from someone who does not himself have specific authorization to utilize genetic resources to another entity for patent or other commercial utilization. In more than half of the publicized claims (most specifically discussed in the Endod, extremophiles, Selva Viva, AMMA Corporation and Millennium Seed Bank cases, but mentioned in many of the other claims),³⁵² the issue raised was whether a researcher with specific authorization to collect samples or undertake research also had the right to authorize others to utilize the genetic resources, biochemical formulas and other results obtained from the samples. Typically, such transfers happened with no inquiry into use rights. Thereafter, sometimes through many years, this research continued without information to the source

country. Later, a patent was obtained or sought based on the material or the research results from the original researcher. This patent or application was then challenged because the original permission did not include any specific right of commercial use of the genetic and biochemical information. In at least seven of the publicized claims (Ayahuasca, Endod (Soapberry), Tricolor Frog, extremophiles, Nap Hal (chapati), Selva Viva, Plao-Noi),³⁵³ the researcher/collector's activity occurred prior to 1992, and in three claims, some product development had occurred before that date.

9.3.5.6 Damages or lack of rights of entry or access for specimen collection

Although frequently identified as a possible basis for claims, relatively few specific claims alleged that the user's action in collecting specimens was not permitted, or that these actions violated the law. In several cases, access issues arose under other law, including:

- Claims generally alleging a violation of normal property rights, such as:
 - trespassing;
 - interference with another person's rights to collect or control specific biological material; or
 - violation of the terms of a concession agreement or license.
- Potential violation of wildlife laws, i.e., claims that it was not legal to capture, kill, uproot, or otherwise gather samples of the biological material collected;³⁵⁴ and
- Claims based on the special rules regarding crown lands, national patrimony or sovereign property (including national parks, specially protected species, and other particular sovereign rights) and the procedures and documents required.

Among the publicly asserted claims, there have been two primary access-oriented bases asserted – that the lands and species held or used by traditional people have been appropriated without permission or compensation; and that, even where the application of ABS requirements is unclear, illegal specimen collection practices should invalidate the rights of the user. This latter type of claim is illustrated by the extremophiles situation (Kenya). In that claim, the direct application of ABS principles was unclear, due to several factors. Instead, the government's claims focus on the fact that the collector, who obtained the samples in a protected area, cannot produce any evidence that he had government permission to take biological material from that protected area.

9.3.6 Objectives of asserting the claim

Consideration of the claimants' apparent objectives underlying their claims provides a valuable basis for analysis of the current level and extent of ABS-related claims. In general, the primary objective and secondary objectives asserted in claims reviewed may be very different, and the selection of the means of asserting the claim can be thought of as the most important method of determining these underlying objectives.

In 28 of the public claims listed in [Table 1](#), for example, the primary claim was based on patent invalidity and sought patent revocation, although genetic resource misappropriation was often asserted as a supporting point. In some of these cases, a final decision has been reached (either invalidating or upholding the patent). Even where the patent decision has gone against the claimants, none have so far indicated any intent to pursue a claim for ABS-related violations.

As noted above, several of the public claims, and a large percentage of the interviews, focus on equity issues, including especially the equitable obligation of a collector or researcher to disclose his intent or decision to transfer the specimens, research results, and other information to a third party after he has undertaken collection and/or research under an appropriate license. A relatively small percentage of public claims and some negotiations and other discussions examined in this study have involved direct attempts to obtain benefits from users of genetic resources. To date, as noted below, uncertainties regarding ABS issues have been perceived as obstacles to direct claims for benefit sharing in courts and formal forums. Consequently, most claimants have focused on other bases for their actions or threatened actions against misappropriators.

9.3.7 Deciding body or governing law

As a final point in this section, the choice among particular legal bases for the claim and the choice of deciding body can be significant in choosing the kind of claim to bring, and evaluating the chances of success of such claims. Selection of governing law and deciding body typically dictates both the objectives that the claim can achieve, and the rights and remedies that should be asserted.

For example, as noted above, more than 75% of the public claims examined were directed at national patent agencies, and were described in terms of that country's patent law. Given that patent law does not generally include any legal mechanism for benefit sharing,³⁵⁵ the final decision of these cases has not yielded any direct judicial analysis or finding regarding whether benefit sharing was required, what standards should be applied, and how they should be enforced.

It is usually necessary to bring any action against a user in the country in which the user lives or operates its primary facilities. A source country or other claimant often cannot obtain legal jurisdiction to bring a lawsuit in any other place. The claimant in such cases, however, is handicapped by the lack of so-called 'user measures' promoting, enabling or even encouraging benefit sharing. This lack of judicial mandate may be another reason that no other court or legislative body in a developed country has specifically addressed the right to utilize genetic resources, or provided decisional support or clarification of benefit-sharing obligations in ABS contracts or under broader principles of equity.

9.4 Extent and impact of misappropriation claims

A variety of different factors underlie each of the claims examined for this report. In many claims, the primary focus of asserted claims has been directed at increasing awareness at all levels. Another group of claims challenge the legality and validity of patents, and others more directly focus on seeking equity and fair utilization of genetic resources. In many instances these allegations have been made together.

This section briefly analyzes:

- Legal and practical issues affecting direct claims of misappropriation;
- The extent to which the results or remedies obtained resolve ABS violations; and
- Claimants' strategic choices in bringing their claim.

9.4.1 Legal and practical aspects of ABS-related misappropriation claims

Claims of misappropriation, whether asserted through a judicial action, administrative process, private negotiations, or a media campaign, can be very costly in time, money and redirection of energy. The effort and cost involved provide an important indicator that stakeholder expectations are so strongly held that they prompt various actions or claims. Where such costs and efforts are to be expended, however, potential claimants must first analyze the chances of particular outcomes, and the value of those outcomes, before finally deciding to go forward with a claim. A number of factors may affect this evaluation. At present, owing to uncertainties regarding ABS law, a claimants' chance of success in ABS claims remains extremely uncertain – a fact that may deter stakeholders from bringing claims. This section considers four areas of uncertainty and their impact on misappropriation claims:

- Uncertainty of legal claims ('grey areas' of ABS and its implementation by national legislation and courts);
- Inconsistency in objective (remedies such as patent invalidation may not be consistent with the benefit-sharing objective of ABS claims);
- Questions regarding scale of alleged actions and reactions (while some cases may involve or allege clear and intentional violations or usurpations of rights, others may arise from misunderstanding or reasonable misinterpretation, leading to a choice of options in the level of the claimants' reaction); and
- The manner in which the above uncertainties impact the claimants' expectations and motivations of their actions.

These uncertainties have a direct impact on the extent and nature of claims that have been brought, to date, relating to unauthorized access and misappropriation of genetic resources.

9.4.1.1 Legal uncertainty regarding resolution of ABS claims

One key factor affecting analysis of the objectives of the various claims reviewed is claimants' ability to take legal action if necessary to protect his/its rights under the existing ABS regime. If the legal system is not predictable, then it will often provide an insufficient basis for a judge's decision. As a result, either the judge will not use the law for decision-making or the decisions will not be replicable or defensible, increasing the number of appeals, and also decreasing future claimants' ability to make a reasonable assessment about the probability of success on their claims – to determine whether it is 'worth the effort' to bring a formal claim, or even to commence informal negotiations, with regard to ABS compliance. Presently, there are gaping areas of legal uncertainty within the ABS regime that make such analysis either difficult or impossible.

This report considers five uncertainties that have been the source of difficulty in resolving claims of mis-appropriation: (1) the nature of genetic resources; (2) the nature of access; (3) the activities that constitute utilization of genetic resources; (4) general inability to reliably detect misappropriation; and (5) the lack of legal provisions in user countries that bind or encourage users to engage in benefit sharing.

[a] Uncertainties regarding the nature of genetic resources

One area of uncertainty regarding the application of ABS principles to a particular claim relates to whether the claim is, in fact, addressing ABS, rather than some other kind of legal concern. Formal legal processes as well as administrative actions both operate through the application of specific laws and principles. In order to issue a ruling or take other legal action,

the court or government officer must begin with the legal issue itself, usually as expressed in a law, decree, act, ordinance, regulation, directive, rule, contract, permit, license or other written legal document. It must then apply this document, in a step-by-step fashion, to the facts of the claim. Hence, the first task of both the claimant and the court will be to determine which law applies to a given claim. ABS law will apply only to claims that involve genetic resources, suggesting that the first question to be answered is ‘Does this claim involve genetic resources?’ If the answer is no, then the claim is not relevant to this study, and the claimant will have to find other legal bases for his proposed action.

Unfortunately, it is not a simple matter to determine whether a claim involves genetic resources because it is not currently possible to know with legal certainty what a genetic resource is. This question arose during the course of this analysis, given that more than half of the public cases examined involved direct use of either:

- Natural products and essences and/or remedies using such products and essences; or
- Naturally or traditionally derived varieties already being used for conventional agricultural purposes (seed trade, agricultural cultivation, marketing of agricultural products, conventional plant breeding and other activities).

A majority of these claims were based on the fact that an individual or company was seeking a patent on a natural or traditional variety or on the use of conventionally derived extracts from plants, animals, microbes or fungi in commercial products. Although clearly valid claims, these allegations did not address ABS or the CBD requirements, instead relying on an entirely separate legal basis – internationally accepted principles of IP law. This body of law will apply to all patent cases, whether they involve genetic resources or not.

Although not using ABS as a basis of their legal action, all of the claims listed in [Table 1](#) identified ABS and the lack of benefit sharing under Article 15 as another possible basis for objection. In interviews, several claimants stated that they did not raise ABS issues more forcefully because they were not certain whether and how ABS principles would apply, or whether their claim involved genetic resources.

This question goes to the heart of the current ABS discussions. From the earliest CBD negotiations, it was clearly expected that ABS should not alter existing functional markets and market activities in biological resources. Farmers, fishermen and forest producers were never expected to share the benefits of the sale of their produce (even though marine products, timber, and agricultural varieties are specifically included within the broad ambit of biological diversity, and all contain genetic resources). Transactions in marine products, animals, forest products, textiles and other commodities containing biological materials in refined form are adequately addressed by long established markets, practices and legal principles. Even the bulk sale of herbal products and extracts collected in wild areas is a conventional type of commerce, adequately addressed by existing contractual and commercial legal systems. These activities are, for the most part, entirely legal and often do not require any kind of government permit or oversight.

To create ABS without disrupting conventional markets in biological products, it was necessary that the CBD must separate the concept of ‘biological resources’ (traditional biological commodities of all types) from ‘genetic resources’ (the genetic and biochemical information of each sub-species or variety, which can become the basis for non-conventional utilization). Therefore, commercial trade in biological material is not subject to ABS, unless

the purchasing party intends to utilize the genetic resources of the species without sharing the benefits arising from that use. This final ('unless') clause, however, cannot be observed objectively, and is very difficult to prove in law.

Few concrete mechanisms have been suggested for determining which activities are normal commercial use of biological material and which are uses of genetic resources. For example, before the CBD was created there were already existing markets in seeds, and systems for the conventional development of agricultural varieties. The relationship between these markets and ABS is somewhat unclear, because it is not certain when activities cease to be sales of biological resources and become the utilization of genetic resources. Some have suggested that GR law applies to new and unconventional uses of biodiversity, in which a user may often need only a relatively small amount of biological material.³⁵⁶ Once the material has been brought into the user country, it can usually³⁵⁷ be reproduced whether chemically (in laboratories), or biologically (in captive breeding or cultivation systems).

As a consequence, it is not possible to control the movement of genetic resources from the source country – the only way to prove a violation of ABS principles is to prove that someone utilized genetic resources. This proof can only be made in the country of use. Legal certainty and binding enforcement of ABS arrangements will depend on whether the distinction between biological and genetic resources is clear, unambiguous and instantly recognizable by governments and other involved parties in all countries – whether a court can make replicable decisions on these matters in a variety of factual situations.

While greater clarity would have enabled claimants to use ABS more actively, this does not mean that it would have increased the number of ABS-related claims. Rather, this kind of clarity would be one step toward enabling all parties (users, governments, communities and NGOs) as well as courts to know when and how to apply ABS to their commercial activities.

[b] Uncertainties about access

Similar doubts arise regarding when and by what action one obtains access to genetic resources. In every legal case or claim relating to misappropriation, one critical question – whether the user has legally obtained access to genetic resources – has been raised. Several questions illustrate this issue:

- *What level of permission is required for access?*

In several of the informal interviews, it was noted that there is confusion among parties to particular claims (including users, government officials, particularly communities, and private landowners) regarding whose permission is required for access to genetic resources. In many cases, the right to physical access to a particular ecosystem has been confused with the right to the utilization of genetic resources found in that ecosystem. Thus, for example, a private landholder or an agency managing a national park believed that it had the power to grant the right to use the genetic resources from specimens collected on that particular property. In most countries and claims, however, the right to control entry into a particular geographic area is thought to be legally separate from the right to control the utilization of genetic material from samples collected.³⁵⁸

- *What happens when the intention of the user changes after the resources have left the source country?*

In more than half of the public cases, species samples were collected by researchers, collectors and others who had no direct commercial intent. Many claims involve samples collected ‘for purposes of research.’ Under some national ABS legislative proposals, there is a specific exemption for such activities. In these instances, claimants allege that permission to collect samples for research did not convey a right to utilize genetic resources in a way that would produce benefits to be shared.

When the users went on to commercialize the GR-based discoveries, they did so assuming that their possession of the samples gave them the right to utilize the genetic resources. In at least seven of the public cases, the ultimate user obtained the specimens and research results from the original collector or researcher, who was based in the user's country or region. The user alleges that he acquired the resources ‘in good faith’ – that is, that he reasonably believed that the person who provided the resources had the right to utilize the genetic resources and was legally able to transfer that right to third parties.

In some cases, resources were taken for non-commercial purposes, such as specimens taken for preservation in a zoo, botanical garden or research institution. If such specimens or their progeny were later obtained by a commercial user, the change in use would raise a similar question – was it necessary to obtain ABS permission for the original collection or only at the time of the transfer or change of use? Concerns about this possibility have been the basis of several public and non-public claims asserted against such non-commercial collections.

- *At what point does access to genetic resources occur?*

In at least seven of the public cases, samples appear to have been collected well before the adoption of the CBD. In these cases, as well, the question arises whether the researcher obtained the right to utilize genetic resources (a concept that did not exist in law at the time) in a manner that produces commercial or other valuable benefits, or only the right to possess the samples or to undertake research on them.

- *Can the user's right of access be rescinded after the user has collected and removed the specimens, if some person later challenges the government's decision?*

In one public claim (Philippine Coral), as well as numerous situations described in individual interviews, users, collectors and catalogers have received formal governmental permission, which was later rescinded or challenged. In nearly all of these cases, the rescission or challenge was based on either (i) concerns that the collector would retransfer the material to a commercial user which would not share the benefits of this use or (ii) claims that the permit process did not adequately comply with national laws regarding public consultation and community consent.

In many of these questions, a basic divergence of understanding is apparent. To many users, the term ‘access’ refers to legal ownership of the biological specimens used in research. A person can legally acquire this kind of access by getting permission from the owner of land to collect specimens on his property, by purchasing specimens from a collector or on the

market, or by cultivating or breeding specimens in his own lands. In the ABS context, however, access refers to 'access to genetic resources' and its meaning is less clear. Article 15.2's provisions about facilitating access to genetic resources appear to refer to the development of source-country law that ensures that access (the right to use genetic resources of the country) can be obtained through compliance with reasonable procedures.

Many national laws and commentators assume that access is a prerequisite of benefit sharing, although the relationship between the two is not specified in the Convention. One question that arises from the review of claims asserted is whether and how they apply to a person who was not required to obtain access to genetic resources in order to obtain samples and/or to begin research. This may have occurred where samples were obtained from an ex-situ collection outside of the source country, or where they were collected prior to the Convention, or bought from an individual who brought samples as biological resources³⁵⁹ into the user country. Will this user still have to share benefits from utilization of the GR?

At present, there are no clear legal answers in any jurisdiction regarding these questions. As noted earlier, however, no formal decisions by courts or formal administrative hearings have been identified which actually consider whether a user had lawfully obtained access to genetic resources prior to use. In the few cases where a formal body has been called to consider ABS questions, the case was ultimately resolved on the basis of other issues (patent, criminal or other law). It generally appears that courts lack sufficient information, either in the CBD or in any national law, to enable them to directly decide these issues.

[c] Uncertainties about utilization of genetic resources

Another area of uncertainty relates to identification of the activities constituting utilization of genetic resources. This issue is, of course, closely tied to the concept of genetic resources themselves, however it focuses on the activities involved. As noted above, numerous claims have been based on the direct use of oils, flours, grains or other extracts milled or taken from naturally occurring or traditionally derived subspecies or varieties. These actions use the properties of the variety (in the same way that commercial trade in fruit juice uses the properties of the fruit), but do not appear to use its genetic resources. Other claims focus on normal kinds of plant breeding (cross-pollination, hybridization, etc.) and animal breeding, which have existed as commercial activities for centuries. Many such claims are adequately regulated under other law, suggesting that they may not need to be covered by ABS law.

The difficulty for purposes of misappropriation claims, relates to finding the point at which a use of the qualities of a biological specimen becomes a utilization of genetic resources. This distinction is difficult. First, in many kinds of GR utilization the relationship between the biological specimen and the ultimate product is becoming less clear. For example, genetic researchers confirm that it is already possible to construct DNA chains from the genetic sequence (the biological notation describing the species genetic make-up) without a reference sample. At present, this process is still expensive, and lack of understanding of the role of other proteins in genetic processes means that a reference sample is still necessary in most cases. However, it is expected that these obstacles will be overcome relatively quickly. It is also already possible to reproduce biochemical properties from many species solely on the basis of their chemical formulas. This capacity is still limited in the case of highly complex formulas, but the threshold of this ability is rapidly changing.

One particular problem relating to the utilization of genetic resources arises from the fact that the original genetic material is generally long gone, by the time a product is created. In many modern GR utilization technologies, genetic resources are used in the creation of the product, but leave no trace within that product. The relationship between the resources and the product in these cases may be difficult to describe in law.

Often, the development of new products is an iterative process. If particular genetic resources are utilized in an early iteration, the user may believe that subsequent stages of development do not utilize genetic resources, and thus do not give rise to benefit-sharing obligations.

In a number of individual interviews, even more difficult claims were described, in which no direct use of genetic or biochemical material or of GRTK was actually involved. Rather, these claims were directed at users who observed the way a particular remedy or natural compound reacted when introduced in humans, animals, and ecosystems, and derived their own compounds to have a similar approach. The resulting compound does not use any genetic or biochemical element of the original species or remedy, but was inspired by research into how biological processes occur within that species. This type of claim, although not formally promulgated at present was mentioned as a potential basis of future claims by nearly 25% of individual interviewees. Its prevalence is evidence of the need for greater clarity about what constitutes the utilization of genetic resources.

ABS enforcement, as currently envisioned, can function only where a source country knows whether utilization of genetic resources has occurred and also what benefits have arisen which the user will be called to share. Only then can the CBD and related national law and legal principles consider whether an equitable share of benefits must be given, and to whom.

[d] Uncertainties about detection of violations and misappropriation

Beyond the problems of definition, there are practical problems of detection. In practice, it is difficult or impossible to identify the biological components of a commercial product by analysis of that final product. In many products of genetic manipulation, more than one biological source material may have been involved. Even if these components can be identified, it is completely impossible to determine where that material has come from.

Consequently, in most situations, only the user will know whether he is using genetic resources, where those resources were obtained, and whether benefits have been derived from them. This inability to recognize misappropriation or unauthorized access by objective evidence has had two impacts on the claims brought relating to genetic resources:

- Source countries and communities have indicated a strong desire to control genetic resource utilization by strictly limiting the ‘access’ end of the transaction, owing to fears that they will not be able to detect unauthorized utilization of genetic resources; and
- Most attention has focused on those compliant users (i.e., those who comply with ABS requirements and/or disclose source of genetic material in patent applications). As further explained in [section 9.4.1.3\[b\]](#) below, these persons and companies are the easiest to identify as potential users of GR (having clearly identified themselves by seeking formal ABS permission, and often by holding public hearings or other public consultation processes to obtain the informed consent of local people). By contrast, as noted in [section 9.2.1](#) above, users who do not comply with ABS requirements are

often difficult or impossible to identify. Consequently, claims directly focused on ABS processes are often directed against compliant companies, creating what is virtually a penalty for compliance in some cases.

These two reactions describe virtually all of the claims analyzed in this report.

[e] Lack of legal rules binding users

Finally, it is useful to recall that ABS focuses on two national commitments:

- On the one hand, source countries commit to:

*creat[ing] conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties.*³⁶⁰

- The corresponding commitment from countries in which genetic resources are used is to promote fair and equitable sharing of the benefits arising out of the utilization of genetic resources³⁶¹ by:

*tak[ing] legislative, administrative or policy measures, ... with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources.*³⁶²

Claims of misappropriation of genetic resources under ABS principles, when asserted against a user of genetic resources, necessarily focus on two questions: Whether the user has complied with any relevant access-related requirements (i.e., whether he acquired the genetic resources legally); and whether he has fairly and equitably shared the benefits he obtained from use of the genetic resources with the source country.

As to both of these questions, however, the entire onus of responsibility has rested with source countries, despite the fact that, as noted above, source countries have no legal right or ability to oversee the actions of users once the resources have left the source country's jurisdiction. Although the CBD has clearly recognised that the responsibilities of ABS rested with both user and source countries, to date, however, each country's national legislation (both in developed and developing countries) place their emphasis almost exclusively on access to the genetic resources of that country.³⁶³ Although many efforts (studies and initial processes for the development of voluntary guidelines) are ongoing, little relevant user legislation has yet been adopted, and most relates solely to enabling voluntary compliance and, more strongly, to controlling utilization of genetic resources that were acquired in the legislating country. At present, developed-country legislation does not appear to address the separate requirement of the adoption of legislation or other measures 'with the aim of sharing in a fair and equitable way ... the benefits arising from the commercial and other utilization of genetic resources,' as required in Article 15.7.³⁶⁴ It is certainly perceived not to support any attempt to enforce ABS requirements of source countries. Claimants seeking remedies or enforcement of ABS principles in these countries, would be forced to use basic provisions of contract and property law, which evolved centuries before any concept of genetic resources as property, and which do not provide any legal basis for ABS actions.

With regard to bringing claims, it is typically necessary in bringing an ABS-related action against a user, to use the law and courts of the country in which the user lives or operates his primary facilities.

This remains a barrier to the use of the legal process to effectuate and enforce ABS commitments, owing to limited user-country legislation directly addressing ABS issues. So far, none of the cases, and none of the interviewed individuals have involved or identified any situation in which a user country has enabled, encouraged or assisted a (different) source country, community or other involved group in obtaining knowledge regarding the utilization of genetic resources, or taken any measures to promote or facilitate benefit sharing. While some cases have been asserted under user-country law, the claimants have not been able to assert these claims under ABS law, given that no user country has adopted legislation clarifying ABS principles, or enabling their application in the countries' courts.

9.4.1.2 Inconsistent objectives: Invalidating patents v. sharing benefits

It is common in law for an initial claim (whether formal or informal) to describe a variety of violations and potential remedies. The claimant will generally begin by presenting the full panoply of possible claims, and then narrow his actual claims and demands over time, in order to eventually come to a final and agreed resolution of the problem. Often, the various claims support one another. However, in some cases, the possible options are inconsistent with one another. Then, the claimant will have to choose one theory to carry forward.

More than 75% of the public claims listed in [Table 1](#) included such a potential inconsistency. This inconsistency pitted the ABS objective (ensuring that where benefits arise, they are equitably shared) against the desire for patent invalidation (which will, in effect, diminish the chance that the user will earn a benefit to share). In essence, rather than asking for a share of the value obtained by the user (the ABS objective), these claims seek to eliminate that user's benefit entirely, for the purpose of protecting existing national markets and market expectations.

This is an important objective, but not directly an application of ABS. Where the user is actually developing a new product based on genetic resources (using new technology), arguably the issuance of a patent will be seen as positive, in that it creates a sharable benefit arising from the utilization of genetic resources, or indicates that one is imminent.

Specifically, such claims differ from ABS in three particular ways:

1. *Subject matter addressed:* As detailed above, many listed on [Table 1](#) do not involve any application of modern scientific principles for the utilization of GR. In fact, where genetic research and development has been involved, patent claims have generally not been brought.³⁶⁵ As noted above, the utilization of genetic resources is a specific and necessary component of any claim of ABS violation.
2. *Harm addressed:* Where ABS allegations generally focus on the user's failure to obtain permission (access) and/or the failure to share benefits, patent claims affirmatively allege financial harm to farmers or indigenous groups or other communities.³⁶⁶
3. *Remedy sought:* Perhaps most important, this question of objective is the single factor most determinative of the success of an ABS-related claim. In patent cases, a finding of the invalidity of the patent must be supported by a general public awareness, so that

the market share or potential is regained. Hence, significant public awareness activities often start even before the patent action is commenced. By contrast, for purposes of asserting an ABS claim by a source country (or other claimant) against a particular user, the most effective bargaining chip in the hands of the source country is the GR-user's interest in avoiding publicity regarding the claim. Given that the ABS remedy is a share in the benefits arising from the use of the GR, the source country or other claimant also has an interest in ensuring that the product is positively received by the market. Consequently, the most productive process will often be a non-public negotiation.

This difference affects more than the choice of theories to be used in promoting the claim. For example, although strategies focused on enhancing awareness effectively use a broad base of NGOs and other members of the public, in a few cases, the role of members of the public has been problematic. In the cases involving the Hoodia, Kenyan extremophiles and University of Lausanne, the publicity may have had an unintended result – restricting the users' incentive to resolve the claim. In each of these cases, the user was initially contacted, and negotiations commenced before there was significant publicity regarding the issue. Arguably, the user might have viewed these negotiations as an opportunity. Any benefit-sharing payments made could be reflected in the user's advertizing materials, corporate reports, and other public statements as a demonstration of social responsibility and cooperation with ABS requirements. After the claim became publicly known, however, this opportunity may have been diminished. The user's remaining objective was simply to quell the protest.

Once claims start circulating, users sometimes feel that 'the damage is already done,' and that efforts to resolve the claim will ultimately lead only to more harmful publicity.³⁶⁷ Hence, where the claimant's object is to obtain a share of proceeds, then, a more discreet opening strategy may yield better results. By contrast, in claims seeking the invalidation of a patent (which would mean that there was no benefit to be shared), greater public outcry may be a more effective choice.

Although raised in public statements, and occasionally in formally filed claims, ABS allegations have not been the factor driving the claim and benefit sharing. As noted above, the legal uncertainties of ABS, compared with the relatively clear and internationally acknowledged principles of patent law (or other law)³⁶⁸ may explain why claimants have preferred patent actions, rather than ABS legislation, as the basis for their legal efforts.

9.4.1.3 Scale of reactions and responses

Two additional points should be noted regarding the nature and scope of claims reviewed for this analysis. First, these claims cover a very broad spectrum from allegations of procedural violations in obtaining or issuing ABS permission (flawed compliance) to allegations of intentional usurpation of the existing rights, varieties, commodities and markets of source countries and local/traditional communities and users. A single broad-brush analysis cannot appropriately consider the significant variations across this scale. Second, however, it is noted that users' reactions to claimants and claims have varied from prompt and productive discussions to rather extreme censure of the claimants. Only a few of the claims examined or described have resulted in a negotiated settlement which enabled the user to go forward with bio-prospecting for, and utilization of, genetic resources.

This section considers the scale of reactions on both sides, and the various levels of the claims and claimants' reactions when compared with the particular harm alleged – the scale of user responses desired in comparison with the particular kinds of claim asserted.

[a] Recognizing different levels of violation

Up to this point, this study has not closely considered the general standard for misappropriation of, and unauthorized access to, genetic resources, looking instead at how various claims have been asserted and how they relate to the ABS process. With regard to the severity of claimed violations involving GR, it is necessary to examine the level of response to each kind of violation.

For example, a user may obtain a permit in compliance with procedures identified in law and regulations, but some local communities may later assert a claim against the government agency issuing the permit, claiming that it did not fully comply with public participation requirements under the law. Arguably, in most such situations, a claim against the user or issuing agency is not usually a claim of misappropriation, but of the procedural violations and other issues to be addressed. However, where procedures were ignored, or intentionally omitted critically interested stakeholders, the 'misappropriation' label may be correct.

None of the publicly asserted claims listed in [Table 1](#) is directed at procedural violations of ABS; however, most individual interviewees from government and industry indicated that fear of procedural irregularities and challenges is a major source of delays in ABS processes.

Perhaps because there are no generally recognized and accepted legal standards for reviewing and deciding ABS claims, the type and severity of the claim has often been determined by the resources (financial, human and other) available to the claimant. Where significant public relations tools are available, claims are asserted through media and public presentations. This result is enhanced where there is some public interest in the species, or a general public dislike or distrust of the user, even if the claim itself is not strong. Where legal services are available to the claimant and where filing fees can be accessed, lawsuits may be filed or threatened. As a result, however, cases which are legally weaker may be filed and stronger ones not, due solely to the availability or lack of opportunity and resources. In some situations, as noted above, claims which might have been more profitably resolved through private mechanisms reached public media through well-meaning 'word-of-mouth' campaigns.

[b] Punishing the compliant

One concern frequently asserted by source-country governments, user-country officials and users relates to the 'automatic penalty' for complying companies. Most of the individuals interviewed indicated that a key tool for locating possible misappropriation are the filings of companies seeking ABS permits, or disclosing the source of materials used in patented products. In other words, companies that have made a good faith effort to comply with the source country's ABS requirements are easy targets for ABS claims, whereas those that have not done so may be harder to identify, even if their violations are much more severe. ³⁶⁹

It has been alleged in interviews and other preliminary discussions in this study, that certain companies (not participating in this study) have adopted specific corporate practices under which they have decided to ignore ABS requirements, because those requirements are

generally unenforceable and violations undetectable. While it is possible that some of these companies' violations will be detected, this is not statistically certain. Moreover, given the issues of legal uncertainty expressed above, these companies often feel safe in ignoring claims asserted against them, even where their use of source-country GR is known or admitted. One objective of the second phase of this study will be to gain a better understanding of corporate compliance programmes, and corporate approaches to misappropriation claims.

9.4.2 Results of claims

The most problematic element of this analysis relates to the results of claims of misappropriation of GR, given that many claims are informal, and that records of claims, even in courts, are often unavailable to international researchers. Hence, it is not possible to provide statistical analysis, or systematic conclusions on the basis of detailed review of the cases and claims involved. This section draws a few basic points from the analysis of the reactions of parties and the results that claims have achieved to date.

9.4.2.1 Formal resolution of claims

Only a few of the claims analyzed or discussed in the course of this research have yet been resolved in any final way. Of the claims that have been resolved:

- Most have been resolved 'by attrition' – that is, the patent or permit or other instrument that was subject of the claim was allowed to expire or not renewed.
- In three instances, an apparently final judicial decision was entered, however none of these decisions addressed the question misappropriation of genetic resources in any way.³⁷⁰ In several other cases, a decision was entered addressing some or all of the claim, after which the claimant indicated the intent to appeal the decision or to continue with the as-yet undecided portions of the claim.
- In two public cases, the authority granting a collector the right to obtain samples, undertake taxonomic work, or catalog traditional knowledge rescinded that right. However, in all of these instances, the rescission was based on the concern that the right-holder would transfer the samples or information to others. These are the primary situations in which misappropriation or potential misappropriation was clearly the reason underlying the final resolution of the claim.
- A small number of claims have been resolved through negotiations.

It should be noted however, that information on the resolution of public claims (especially those identified as 'public outcry,' 'public disclosure,' 'threatened case/claim,' 'demand,' etc.) is sometimes difficult to obtain. Users are often unwilling to say anything, fearing to reopen a dormant issue, and in many cases the primary focal points acting on behalf of the claimants have not been located. Only a few of the claims identified in this study are specifically known to be still active in courts or private negotiations. In some of these, although private negotiations are officially ongoing, participants indicate that the talks have basically ceased.

9.4.2.2 Claimants' reactions

As noted above, there is a relatively high level of uncertainty in asserting a claim of misappropriation. In addition, claims are generally quite costly, whether in money or in the

commitment necessary to assert a claim either legally or through active publicity. These factors suggest that claimants asserting ABS violations and other related harms are highly motivated in this endeavor. The range of claimants identified in this study includes governments, indigenous communities, local residents, landowners, NGOs, and in a few cases industrial users complaining against other users. Their motivations and expectations are another critical factor that must be considered in this analysis.

Leaving aside the claims that are brought under internationally accepted principles of patent law, the range of expectations motivating persons to assert claims of misappropriation and other ABS violations generally include:

- Financial motivations – the receipt of an equitable share of benefits arising from the use of GR;
- Promotion of the interests of traditional and rural people, and source countries with limited resources; and
- Promotion of the CBD objective that the benefits from utilizing genetic resources can provide a resource base to finance the necessary actions described in the convention, as well as an incentive to conserve and sustainably use biological diversity.

The strength of these commitments can often mean that claimants alleging misappropriation are much less pliant than the types of claimants normally encountered in commercial operations. Where they are acting on behalf of the environment, indigenous groups, and future generations, claimants often feel that compromise is not an option.

9.4.2.3 Users' reactions

In comparing the public claims ([Table 1](#)) and the individual interviews, the most significant difference is in the level of information available regarding users and collectors. The publicly available information regarding claims is almost entirely offered from the claimants' point of view. Where any public information is available from the users regarding a particular claim, it is usually very brief, and limited in content.

The individual interviews generally suggest that this lack of public information is based on a belief that the publicity will die down more quickly, if the user remains silent. In individual interviews, many representatives of user companies indicated that they would rather keep silent than present evidence of the propriety of their actions, because they felt that any public statement would continue the controversy. Similar to their belief that ABS compliance often made them a target of claims, more than half of those interviewed felt that responding in good faith to public claims only increased the amount of negative publicity they received.

As noted earlier, companies indicated that they are much more likely to negotiate regarding a misappropriation claim, before negative publicity has begun. One incentive for a commercial company to engage in ABS negotiations arises from the company's expectation that it can describe the ultimate resolution as 'social responsibility' in its corporate reports and other public statements.

One of the most important user reactions to claims of misappropriation has been a collective reaction – the desire to develop a generally accepted standard of behaviour for companies engaging in bioprospecting and other utilization of genetic resources. In some cases, these industry-based endeavors have begun to fill the gap created by user countries which have not

adopted legislative, administrative or policy measures for benefit sharing. One example of this is the work of the Japan Bio-industry Association, in conjunction with the Bio-industry Division of Japan's Ministry of Economy, Trade and Industry, in the development of Guidelines on Access to and Benefit Sharing of Genetic Resources.³⁷¹ These guidelines are specifically intended to help eliminate misunderstandings leading to claims of misappropriation. This document offers a concrete first step toward effective user measures, given its provision stating that, if a user, researcher or collector complies with all of these guidelines and still encounters claims of misappropriation, unauthorized access or biopiracy, the Japanese government will use informal and diplomatic means to seek a solution to the problem. This assurance of user-country government assistance in resolving ABS-related claims offers real value to the user companies, and may become a primary incentive, encouraging compliance with these (voluntary) guidelines.

9.5 Summary and conclusion

As noted at the beginning of this article, it would be inappropriate and unproductive for a single author or even team of authors to attempt to characterize any unadjudicated claim as misappropriation or unauthorized access (or some other conclusion), based on its own review. Instead, this study has examined the extent to which claims of misappropriation of genetic resources or unauthorized access have arisen, and their relationship to ABS activities and legislation. This concluding section of this analysis begins by summarizing the objective results of the study. It follows with an analysis of the two primary questions posed by COP Decision VII/19 – the extent and level of claims of misappropriation.³⁷² Finally, it presents a brief suggestion of lessons learnt, based on information received to date, in terms of direct strategies for resolution of ABS claims, the impact of such claims on ABS practice, and the relevance of this study to the negotiation of the international regime.

9.5.1 Claims and cases reviewed

The claims analyzed by this report include formal legal proceedings, claims asserted administratively, and claims asserted informally (through media, direct demand on users and user governments, and in other ways). Information concerning these claims was discerned through publicly available (primarily electronic/internet) sources and through interviews with individuals from government, industrial and commercial entities, research institutions, NGOs and groups representing indigenous communities.

Formal judicial cases and decisions: Most of the claims identified through this research have not been adjudicated. Many will never be. Of those that have been before the courts, none has been expressly decided on the basis of ABS. To date, no case has been found that has actually decided issues clarifying the right of the user to utilize genetic resources or GRTK and/or the right of the source country or indigenous group to receive a share of benefits from that use, primarily because claimants have not attempted to bring actions under ABS legal theories, which are currently very indefinite in legal terms.

Formal administrative processes: Records of administrative claims have been difficult to acquire; however, in the course of this study, numerous individuals from governments, industry, academic/research institutions, NGOs and indigenous representatives have provided informal descriptions of their experience with formal objections to ABS applications and permit processes. In general, interviewees indicated that such claims frequently allege that the user's activities constitute a misappropriation of genetic resources or GRTK. Many of these

claims may be based on a requirement in national law, which mandates public consultation, holding that if this law is not complied with correctly, the resulting permission is not valid. In other cases, the claim alleges that the government negotiators have not exercised due care in protecting the sovereign rights and property interests.

Informal claims and results: The majority of claims discerned in this study have not been formally presented in courts, and many of them have not been submitted as formal objections or interventions in national administrative procedures either. Two informal mechanisms for asserting claims of misappropriation were found to be key:

- *Use of news media and other public awareness tools:* This study has not been able to investigate these activities at local levels, but has discussed their use through informal interviews. In many instances, public disclosure of particular activities and, more specifically, public outcry against those activities have been reviewed and discussed.
- *Direct demand/request:* Another mechanism has been direct appeal to the user, cataloger, researcher or other person against whom a claim of misappropriation is contemplated. Typically, this mechanism is most effective when it is not publicized. Hence, in this analysis most discussion of this kind of claim has been through individual interviews. This mechanism is the least used of the mechanisms examined in this report. It has primarily been used by governments and indigenous groups, in cases in which no ABS compliance has occurred, where some violation of the terms of ABS permissions has been alleged, or where there is a misunderstanding about whether ABS and other laws apply to a given activity.

9.5.2 Analysis: Extent and level of claims

Given the manner in which information was collected, numerical analysis of the extent of claims is somewhat difficult, and possibly not productive.³⁷³ More broadly, reliable information on the number of ABS agreements that exist or have been negotiated to date is not available, and it is nearly impossible to determine how many instances of commercialization or other informal use or access to genetic resources have occurred.³⁷⁴ Consequently, even if numerical analyses were possible regarding the number of claims, it would be difficult to convert them into usable statistics, given the need to relate them to the frequency and nature of other ABS activities. Comments on the extent of claims must therefore remain somewhat subjective at this stage in the analysis, although it may be possible to develop more focused analytical samples in the second phase of this study, from which a limited form of statistical evaluation may be possible.

9.5.2.1 Extent

Regarding the extent of claims, several persons have suggested that there are very few claims.³⁷⁵ Upon investigation, this comment is usually addressed at claims asserted in formal lawsuits before courts, patent agencies and similar bodies, and as such, tallies with the results of this study's inquiry into public claims, of which only a small number of formal claims were discerned and, relatively speaking, only a small number of informal public claims, as well. In general, however, the number of informal claims and complaints that have not been broadly publicized at national and international levels, as well as claims asserted through source-country administrative agencies and processes, appear to be relatively numerous in all developing countries in which ABS processes are authorized. It has also been suggested that

the number of claims increases proportionally with the increased awareness of NGOs, indigenous groups and others with regard to ABS issues and genetic resources.

A significant number of cases and claims examined or discussed in this study involve very basic disputes – that is, the person or entity that is the subject of the claim does not believe that the claim is true or applicable. This suggests that the number of claims may diminish if a set of objectively determinable standards for ABS compliance (including for determining when ABS compliance is required) can be agreed at international and/or national levels.

9.5.2.2 Level

The level of claims identified in this study raises a few very interesting points. Most notably, few claims are formally asserted in courts, despite a relatively high level of effort that is directed toward public disclosure, public outcry and informal challenges. This suggests that the current lack of specific objective rules, standards, definitions and procedures is raising high levels of concern, while also decreasing the level of certainty among claimants regarding whether and how their claims will be addressed by courts and formal processes.

This conclusion is buttressed by the facts discerned in this study. Nearly all formal claims asserted have chosen to challenge patents and patent applications, rather than to address ABS compliance issues. Given that well settled international principles exist with regard to patents, claimants find it easier to assess their chances and evaluate whether it is worth the effort to bring a formal patent claim (as compared with bringing an ABS claim, on which little or no concrete law exists, and no prior claims can be used as a basis for evaluation).

In terms of impact, many corporate representatives and researchers interviewed indicated that the impact of an informally asserted claim (through news, internet and other media) can have a very serious impact, which can be very long-lived. Negative publicity impacts (being labelled a ‘biopirate’) are difficult to repair, even after the company has altered its behaviour. News stories rarely address such actions, or promote them with the same intensity as the original claim. Although indicating a high potential impact of some claims, this point also raises a concern. Companies which might have been willing to resolve ABS claims through benefit-sharing negotiations are less inclined to do so where claims have been made public.

9.5.3 Analysis: Lessons learnt

The lessons learnt from this initial analysis are somewhat diverse, and not yet fully documented, however some key points have become clear that may have relevance for the resolution of ABS claims and for the international regime negotiations.

9.5.3.1 Strategies for resolution of ABS claims

It is not yet possible to consistently or defensibly analyze the interconnection between the claims asserted and the achievement of ABS objectives. Some common issues and concepts suggest two possible lessons relating to resolving of claims of misappropriation of genetic resources.

First, most claims reviewed arise in part from uncertainty about ABS requirements and the lack of objective standards for determining whether a user is authorized to utilize genetic resources. Many users question whether they are responsible under the source-country's ABS

regime at all, given that they obtained access to the genetic material from a researcher or other person who was based in the user's country. These basic unresolved questions stand at the centre of many disputes and claims relating to misappropriation, suggesting that such claims could be more easily resolved and addressed by resolving the existing uncertainties, and developing a set of legally clear, objective and replicable standards for evaluating ABS compliance. While such a standard would be of value in courts and other legal cases, its greatest value would be outside of such processes, where it would enable all parties (government, industry, and citizens/indigenous people/NGOs) to know more clearly where issues and concerns exist that are valid and need to be addressed and resolved.

Second, it appears that most negotiations between commercial users and ABS claimants have been unproductive. Even where negotiations are ongoing, the parties have been very negative regarding the prospects for solution. Based on this initial study, it appears that this lack of results arises because the two sides of the claim are operating on very different levels:

- Most commercial users view ABS as a mechanism of commercial law. A legal analysis of its contents (in the CBD, national law and contracts) indicates its role as a legal tool that applies in transactions involving genetic resources from a source country. Negotiation of ABS claims is seen as a normal commercial negotiation.
- By contrast, many claimants alleging misappropriation of genetic resources may view ABS as a tool for achieving social and environmental equity, and for ensuring the rights of future generations to a healthy and biologically diverse world. Others see their claims as a way of ensuring that the government's ABS decisions are taken at the highest level of fiduciary responsibility – that stewardship of its sovereign rights in natural and genetic resources protects the rights of all citizens, present and future. Here also, the CBD and ABS-related COP decisions indicate a clear intent that ABS should operate as an incentive mechanism promoting conservation and sustainable use of biological resources by promoting equity among user and source countries.

Hence, where the user may perceive a particular claim to be a single negotiation over a single asset or activity, the claimant may see it as a cornerstone of a much larger social system. This point is underscored by numerous interviews in which users complained about the claimants' unwillingness to conform to basic standards of commercial negotiations, while claimants objected to the users' expectation of a prompt commercial compromise of key social issues. Consequently, it seems important for the discussions and developments relating to ABS and GR use to move beyond generalities, clarifying both sets of issues and integrating them into a reasonable operating structure.

9.5.3.2 Relevance for the negotiation of an international regime

Remembering that the international community is in the midst of extended discussions aimed at negotiation of an international regime on access and benefit sharing under the CBD, it seems particularly important to underscore the manner in which the lessons learnt from this study could be useful to those negotiations:

Lesson 1: While a full range of policy-related issues are being considered in the negotiations, in practice, utilization of genetic resources is ongoing. The level of utilization generally seems to be cyclical. As recently as 2001, in AHWG-ABS-1, industry participants and others were strongly claiming that bioprospecting and GR utilization was declining. Throughout this study, these same groups have stated that it appears to be increasing. *This suggests that, in*

addition to addressing overarching policy issues in detail, priority could be given to development of a technical annex, which can resolve confusion by, for example, re-stating existing ABS provisions as legally certain and objective standards, definitions and processes. (This may also indicate the need for capacity building with a view to assisting in the development of national ABS regimes).

Lesson 2: In general, claims of misappropriation and unauthorized access often proliferate as a result of uncertainties and basic disagreements about whether it is necessary to comply with and negotiate regarding ABS requirements, in particular addressing the questions regarding the acquisition of genetic material through a secondary transaction (from a researcher, cataloger, or collection outside the source country). *An agreed set of step-by-step procedures for use at the national level would provide certainty for both user and provider regarding whether the use was authorized. While such procedures should be adopted at the national level, the international regime negotiations can address the existing grey areas (including the nature of access and the responsibilities of those who have acquired research and collection rights without acquiring the right to utilize genetic resources – i.e., by transfer of samples and research results from third parties who may not have acquired the right to utilize the genetic resources involved).*

Lesson 3: Although many developed countries are addressing access to their own genetic resources, and some have begun to evaluate ‘administrative and judicial remedies available [regarding] users under their jurisdiction,’³⁷⁶ relatively few have adopted any “legislative, administrative or policy measures, as appropriate ... with the aim of sharing in a fair and equitable way ... the benefits arising from the commercial and other utilization of genetic resources,’ as required under Article 15.7. *In concert with measures adopted in source countries, user-country measures are a primary necessity in order to enable ABS to function. Such measures could provide a primary source of clarification for source countries in negotiating ABS agreements, thereby eliminating another source of the uncertainty which encourages the public filing, publicization and non-public assertion of claims of misappropriation.*

Lesson 4: A significant problem arises out of the perception that ABS, in effect, penalizes compliant companies (as more clearly explained in section 9.4.1.3[b] above). As both a consequence and indicator of this, it appears from this research that companies which comply with ABS and other government requirements bear a much higher burden of non-patent-law misappropriation claims coupled with the industry reaction that public outcry and disclosure eliminate all remaining desire to resolve ABS complaints. This problem is the lack of real commercial/practical incentives to encourage users to comply with ABS requirements. The difficulties for all parties involved in bringing claims and negotiating their resolution can never be fully addressed through a command and control system. *The international regime can best address problems of non-compliance in conjunction with claims of misappropriation through (stepwise) development of incentive measures (actions and objectives that have a real impact on users).*

ANNEX 1 to Chapter 9 – Public claims identified (additional detail) ³⁷⁷

Inf Genetic o resource lev and other el identifiers –	Source country	Primary user information – Entity	Claimants	Traditi onal Knowle dge	Type of claim	Time period	Curre nt status
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	traditional/common name of spp. scientific name of spp. (name of isolated compounds; products, comm'l or research use)		name (user country)		(D=direct G=GR TK) ³⁷⁸	
High	Ayahuasca Banisteriopsis Caapi (product name "Da Vine")	Ecuador	Loren S. Miller; International Plant Medicine Corporation (USA)	NGOs representing indigenous interests (ILC, COICA, Amazon Coalition, CIEL and a coalition of 18 Amazon region NGOs)	D	1974 – samples collected 1986 – patent filed 1999 – No longer active Formal case/claim filed 2002 – patent expired according to its terms
High	Basmati	India	RiceTec Inc. (USA)	Gov. of India through Agricultural and Processed Food Products Export Development Authority (APEDA); and three individuals representing Indian NGOs	D	Product marketed around the world for many years – no specific collection date 1997 – patent filed 2000 – case filed 2002 – claims withdrawn Formal case/claim
High	Cunani and Tipir (product name:)	Brazil	Conrad Gorinsky, researcher (UK);	Wapishana (indigenous) community	D	Early 1990s – samples collected 1994–2000 – Closed

	“Cunaniol”)		Biolink Ltd, Corp. (Canada)			patents filedPost 2000 – case filed 1964 – sample collection1 993 – patent obtained19 93 – initial public outcry2001 – patent expired according to its terms	
Hi gh	Endod or Soapberry, Phytolacca dodecandra	Ethiopia	University of Toledo (USA)	ETC Group; Coalition AgainstBio piracy (internation al NGOs)	G	Public outcry	No longer active
Hi gh	Yellow Bean, including varieties “Azufrado” and “Mayocoba” (product name “Enola bean”)	México	Larry Proctor, Pod-Ners Inc. (USA)	Gov. of México; Int’l Ctr for Tropical Agriculture (CIAT); ETC Group	D	Formal case/clai m	Pendin g
Hi gh	Tricolor Frog (active compound – alkaloid 208/210,pro duct names “the ABT- 594,” “Epidat”)	Ecuador	US National Institute of Health; Abbott Laboratorie s (USA)	Acción Ecológica (local NGO)	G	Threat ened case	Unreso lved
Hi gh	Kalahari Hoodia, Hoodia gordonii (product name “P57”)	Namibia, RSA, Zimbabw e	Council Scientific and Industrial Affairs (Rep. of South Africa) Successor corp: Pfizer Corp.; Phytophar m Corp.	SA lawyer acting for the San People, ILC; Action Aid (local NGO)	G	Threat ened case	In negotia tions

M ed.	Extremophiles (product names “IndiAge Neutra” and “Puradax”)	Kenya	University of Leicester (UK); Dr William Grant, researcher (UK); Genencor.	Gov. of Kenya through Kenya Wildlife Services	None	Threatened case	1992 – sample collection 2002 – commercial product described in corporate annual report	In negotiations
High	Maca Lepidium meyenii (product name “MacaPure” and others)	Peru	Pure World Botanicals; and Biotics Research Corporation, (USA)	Gov. of Peru through the National Working Group; Peruvian Coalition Against Biopiracy (coalition of local indigenous and farmer NGOs)	D	Public outcry	No information on date or kind of access/sample collection; 2000 and 2001 – patents issued on two compounds	No resolution yet
High	Nap Hal wheat variety used in chapatis (product name “Galatea”)	India	Unilever/Monsanto Corp. (Multinational, EU patent)	Research Foundation for Science, Technology and Ecology (local NGO); Greenpeace (international NGO)	D	Formal case/claim	No info on date of access (from ex-situ collections) 1991 – patent application 2003 – patent obtained 2004 – claim filed	Decided 2004 patent invalidated
High	Neem Tree	India	W.R. Grace Corp. (USA); US Department of Agriculture	RFSTE (local NGO); Green Party (EU Parliament); IFOAM (international NGO)	G	Formal case/claim	No info on date/type access 1994 – patent granted and claim asserted 2002 – patent revoked	Decided 2002

High	Pozol (isolated compound: <i>Bacillus subtilis</i>)	México	Quest International Corp.; Univ. Minnesota (USA)	Global Exchange (international NGO); ETC Group	D	Disclosure Possible other action	1990s – access to TK and GR1999 – patent granted 2003 – patent expired	No longer active
Med.	General prospecting for species or compounds	Brazil	Selva Viva (Switzerland), and successor (multinational) corporations – Ciba-Geigy, Hoechst, Sandoz, Lilly, and Johnson & Johnson.	Gov. of Brazil, through Deputy Edvaldo Magalhaes, Acre (province) Public interested groups, from Acre (including Roman Catholic Church officials, Indigenous Missionary Council (CIMI); and Indigenous Nations Union (UNI-AC))	G	Formal case/claim	1980–1996 (approximately) – biological prospecting activities commenced 1996 – case filed	Apparently resolved
High	<i>Swartzia madagascariensis</i> (isolated compound “antimicrobial diterpenes”)	Zimbabwe	Univ. Lausanne (Switzerland)	Community Tech. Dev’t Trust; and Zimbabwe Traditional Healers Ass’n (Zinatha) (local NGOs); Berne Declaration (Swiss NGO)	G	Demand	1995 – access through research agreement 1999 – patent granted (USA) 2003 – patent expired according to its terms	No longer active
High	Turmeric	India	Univ.	Gov. of	D	Formal	No specific	Decide

gh	Curcuma longa		Mississippi Medical Centre (USA)	India through Center for Scientific and Industrial Research, Dept. Science & Tech.		case/claim	date of access 1995 – patent granted 1996 – claim filed 1998 – patent invalidated	d 1998
M ed.	Acai Euterpe precatoria (multiple product names such as “Acai Power”)	Amazon region	Unspecified holders of “Trademarks in North America and Europe”	Acción Ecológica	D	Public outcry? Or formal?	2001 – trademark protected EU and US 2002 – US trademark abandoned 1994 – ethnopharmacological study published Before 2004 – patent application 2004 – public statement	Unresolved
Low	Traditional plant medicines	Peru	AMMA Corporation	Coalition Against Biopiracy, on behalf of Suni-Mirano people	D,G	Public disclosure of patent		Unresolved
Low	Andiroba Carapa guianensis Aubl.	Amazon region	Unspecified holders of “patents registered in North America, Europe and Japan”	Various sources, including Amazon-link.org (Brazilian NGO)		Public disclosure of patent		
Low	J’oublie berry (patented product name “Brazzein”)	Gabon (and West Africa generally)	University of Wisconsin (USA)	Unspecified countries of origin	G	Public disclosure of patent	1994–1998 – four patents granted 2000 – public statements published	
M ed.	Philippine Snail Conus magnus (compound	Philippines	Neurex Inc., (US); Univ. Philippines,	Civil society organization		Regulatory challenge	Patents granted (US patent numbers	

	known as “SNX 111”)		Marine Science Inst.; and Univ. Utah				5189,020; 5559,095; and 5587,454) Samples obtained/re moved 1999 – penalties assessed, permit obtained, permit cancelled
M ed.	Unspecified bioactive coral	Philippine s	Bristol- Meyer Squibb	Government	None	Formal claim/c ase	
Lo w	Copaiba Copaifera sp.	Amazon region	Unspecified holders of patents [that] have been obtained	Various sources including Amazon- link.org, (Brazilian NGO)	D	Deman d	Public demonstrati ons
	Cupuacu Theobroma Grandifloru m	Amazon region	Unspecified holders of patents in Japan (Japanese trademark number 4126269 CUPUAÇU) and Europe (patent request EP1219698 A1 on Cupuaçu oils and chocolate at the European Patent Office)	Various sources including Amazon- link.org	D	Formal claim/c ase	
Lo w	Jamun Syzygium cuminii, Karela (Bitter Melon)	India	Cromak Research Inc. (USA) and three individuals	Various sources including Vedana Shiva	Various	Public disclos ure of patent	[Prior to 1999] – patents granted (US Patent No.

	Momordica charantia Lin and Brinjal (Indian Aubergine/eggplant) Solanum melongena L Bitter Gourd - called “Bird Droppings Gourd” in Thai (isolated compound “MAP30”)	Thailand		G		5,900,240)	[Patent in the US]
Low	Hom Mali (Jasmine Rice) (product name “Jasmati”)	Thailand	US Dept. Agric.; RiceTec	Thai farmers, lawyers, NGOs (calling for Thai Govt involvement)	D, G	Threatened claim/case Demand	1997 – trademark approved “Jasmati” 2001 – protests against USDA research activities
Low	Kemukus and Sambiloto Andrographis panicurata	Indonesia	Shiseido corp., (Japan)	A group of (undisclosed) NGOs	D	Public disclosure of patents	Prior to 2000
Low	General collection of seeds (Millennium Seed Bank Project)	Kenya	Royal Botanical Garden – Kew	Various local NGOs and others	Unspecified	‘Regulatory’ challenge	1999 – negotiation opened 1999 – public concerns expressed
Low	Nuna Bean	Andean region	Appropriate Engineering and Manufacturing		D		Resolved
Low	Other patents	Amazon region		Various sources	D	Public disclosure	

Low	<p>noted: Cat's Claw Uncaria tomentosa, Maca Lepidium meyenii, Sangre de Drago Croton lechleri, Quebra Pedras Phyllanthus niruri, and Wormseed Chenopodiu m ambrosioide s Other patents: tamarind, haldi, ginger, anar, India pepper, and amla have all been patented.</p>	<p>including Amazon- link.org</p> <p>Various sources including Vedana Shiva</p>	<p>ure of patent</p> <p>D</p>

³²⁰ The third objective is ‘the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding’ (CBD, Art. 1).

³²¹ The primary ABS-related commitments of the Parties are found in Articles 15 (all), 16.3, 17.1 and 2, 19.1 and 2, 20.1 and 3, and 21.4. A well-constructed functional ABS system may support and further a great many CBD objectives (see Young, T.R. 2004. Options and Processes for the Development of an International Regime on Access and Benefit Sharing, at 5 and 20–21. IUCN/BMZ).

³²² For purposes of saving paper, the author will use the single word ‘misappropriation’ as shorthand for ‘unauthorized access and misappropriation of genetic resources and associated traditional knowledge.’ As noted in [Tables 1](#) and [3](#) (and [note 329](#)), this chapter interprets those terms very broadly. Where more specific terminology is needed, it will be so noted in text.

³²³ CBD COP Decision VII/19, Clause E.9(c).

³²⁴ A private individual or organization making statements that a specific action is ‘misappropriation,’ in a public forum such as the CBD, might potentially be subject to legal action.

³²⁵ In recent years, the terminology issue has become increasingly controversial, with initial pejorative terms such as ‘biopiracy’ being replaced by terms like ‘unauthorized access’ and ‘misappropriation’ which are also becoming controversial. Recently, less evaluative terminology has been proposed – Robert Lettington has coined the term ‘irregular access,’ as a descriptive that does not carry any suggestion of fault or liability, but only the existence of questions which must be reviewed.

³²⁶ The literature is replete with discussions, particularly of the journalistic term ‘biopiracy.’ Perhaps most interesting, and one of the few official, of these is the Africa Group’s submission to the WTO’s TRIPS Council (available online at <http://docsonline.wto.org/DDFDocuments/t/IP/C/W404.doc>). See also, Gollin, M.A. 1999. ‘Biopiracy: The Legal Perspective.’ *Nature Biotechnology* 17 (September), and presented to the American Society of Pharmacognosy in 1998. Washington DC: American Institute of Biological Sciences (available online at <http://www.actionbioscience.org/biodiversity/gollin.html#Primer>); Dutfield, G. 2004. ‘What is Biopiracy.’ Proceedings of the International Expert Workshop on Access to Genetic Resource and Benefit sharing (Canada/México, 2004). Dutfield generally concludes that biopiracy remains ‘an impressive term for which most actors have their own definition.’ Legally focused definitions of ‘misappropriation of genetic resources’ are found in Nnadozie, K. and R. Lettington. ‘A Review of the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore at WIPO.’ (http://www.ciel.org/Publications/Occassional_SouthCentre_Dec03.pdf). T.R.A.D.E. Occasional Paper No. 12. South Centre/CIEL. See also ‘Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement,’ a Joint Communication from the African Group, submitted by the Permanent Mission of Morocco to the TRIPS Council meeting on 4–5 June 2003 (available at http://docsonline.wto.org/gen_home.asp?language=1&_id=1 – choose ‘search for document’ and search for ‘document symbol’ IP/C/W/404), noting that ‘such misappropriation has taken the form of obtaining patents in developed countries inconsistent with the will of the communities and countries that have sovereignty over the resources.’ These definitions and discussions, while perhaps of value academically, do not clarify the issue examined in this paper.

³²⁷ As noted above, this study is still in its initial phase, and has been funded to continue work in greater detail. Additional research and confirmation of current status of all claims will be undertaken.

³²⁸ A more detailed table is included as [Annex 1](#) to this Chapter. For this paper, standard legal details (which court, legal theory etc.) are not relevant. This table identifies instead the form of each claim – a formal case (filed legal action), a threatened case, a regulatory challenge (governmental processes), a demand (informal assertion), or a public outcry (public statement), or public disclosure of the existence of a patent of possible concern.

³²⁹ Most of the terms being searched can be found in the columns labelled ‘Genetic resource and other identifiers,’ ‘Primary user information’ and ‘Claimants’ in [Annex 1](#).

³³⁰ A similar problem arises for source countries seeking information on use of genetic resources. Even in patent databases, one might have to search each species individually (by common and scientific name) to see if it appears in a patent application, and even this cannot catch all uses. A good analysis of the methodology needed for use of patent databases as sources of information on genetic resource use, and the unavoidable limitations of such a methodology is found in Oldham, P. 2004. 'Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology.' Global Status and Trends in Intellectual Property Claims 1. Available at www.cesagen.lancs.ac.uk/staff/oldham.htm

³³¹ Although key information can be found in public filings and other separate databases (such as those recording patent applications, and governmental databases of court filings and cases), these sites, if reliable and comprehensive, are priced in a way that prevents the necessary levels of sampling.

³³² It has been difficult to identify and locate specific representatives working on particular claims.

³³³ Several ABS contracts have been provided in confidence to The ABS Project, a project being implemented by IUCN ELC with funding from the German Ministry for Development Assistance (BMZ); additional information has been provided in interviews. In addition, numerous form agreements have been provided which significantly omit any provision limiting the Parties' rights to disclose the contents or terms of the agreement. The ABS Project is preparing a detailed analysis of existing ABS Contracts, with the goal of providing a guide to the legal issues arising in the negotiation and documentation of ABS contracts. This information will be published in a forthcoming book: Carrizosa, S., S. Bhatti et al., Contracting Science – Examining the Contractual and Scientific Issues Relevant to ABS Contracts and Legislative Development (IUCN, expected 2008). Additional information regarding The ABS Project and its forthcoming publications may be found at www.iucn.org/themes/law or by contacting the Project manager at tomme.young@gmail.com

³³⁴ As one industry representative noted, 'the less we say about these issues, the better. In many cases, even if we have strong and credible information that combats a claim, we don't present it in the media, because it will just keep us in the middle of public attention, and discussions of 'biopiracy' in the news media always present the industry as a 'bad actor,' no matter what the facts are.'

³³⁵ Libel is normally defined as 'defamation by written or printed works, pictures, or in any form other than by spoken words or gestures' or 'the crime of publishing [statements that constitute libel as previously defined].' Webster's Encyclopaedic Unabridged Dictionary. Further relevant legal concepts address situations in which an unfounded claim causes the loss of a legitimate commercial opportunity.

³³⁶ Note that this table identifies the percentage of respondents who discussed or described experiences involving each type of claim. Obviously, many respondents had experience with more than one claim.

³³⁷ Some of those who did not formally respond noted a need for more time to compile their response, but several indicated a need for a clearer idea of the nature of the inquiry and of the manner in which it will be used. It is hoped that this report will answer some of those

questions. Following its completion, it is intended that IUCN-Canada will undertake a survey of relevant stakeholder groups (government, NGO and user) to develop a more robust body of data on these issues.

³³⁸ The ‘Other’ category includes primarily cataloging projects and specimen collections (botanical gardens, zoos, herbaria, and seed collections). All persons interviewed had direct experience with claims involving ABS transactions.

³³⁹ Recognizing that no official documents have been available for many of these claims, and not all possible avenues of information have yet been completely reviewed.

³⁴⁰ As described in the CGIAR website at www.cgiar.org/who/index.html.

³⁴¹ See, Moore, G. and Tymowsky, W. 2005, Explanatory Guide to the International Treaty on Plant Genetic Resources (IUCN/IPGRI), at 90.

³⁴² The service (or at least its outreach component) appears to be managed by IPGRI. Information on the CAS can be found at www.ipgri.cgiar.org/cas/Default.asp

³⁴³ Such objections are relatively common in ABS negotiation processes, however, the objective of such a process is to ensure that the applicant does not engage in misappropriation and that his access is authorized. Hence, these are not claims of misappropriation for the purposes of this study.

³⁴⁴ As noted below, many users are not aware of any obligation to obtain access having acquired the genetic material from researchers and others within the users' own country. Hence, further negotiation over access requirements is often unproductive, however, direct negotiation relating to benefit sharing may be useful.

³⁴⁵ Art. 15.7.

³⁴⁶ In recent years, the terminology issue has become increasingly controversial, with initial pejorative terms such as ‘biopiracy’ being replaced in CBD discussions by terms like ‘unauthorized access’ and ‘misappropriation.’ Unfortunately, although intended to be less prejudicial, these terms too are sometimes sometimes objected to as controversial. Recently, even less evaluative terminology has been proposed – Robert Lettington has coined the term ‘irregular access,’ as a descriptive that does not carry any suggestion of fault or liability, but only the existence of questions which must be reviewed.

³⁴⁷ The Yellow Bean and Ayahuasca cases, described in [Annex 1](#), are examples of these situations.

³⁴⁸ See for example the Neem Tree, basmati rice, jasmine rice, and Nap Hal claims described in [Annex 1](#).

³⁴⁹ As with all other ABS issues, the relationship between ABS cases and traditional knowledge cases involves difficulties of legal analysis not present in other ABS matters. It is also noted that the patent issues relating to traditional knowledge cover a wide range of matters far outside of the scope of ABS, and that the legal basis for TK actions is significantly different from that relevant to ABS claims (see for example the significant

differences in wording of articles 8(j) and 10(c), as well as articles 17.2 and 18.4). Hence, although ABS law and TK law will frequently overlap, in terms of framework development and legislative/judicial implementation, they must be thought of and addressed as two separate legal theories. For the purposes of this paper, the instances in which the two issues clearly overlap and must be addressed together are referred to as ‘genetic-resource-related traditional knowledge.’

³⁵⁰ By contrast, situations in which the subspecies/variety or remedy was directly used or marketed fall within the broader category of ‘utilization of traditional knowledge,’ but may not be GRTK.

³⁵¹ For purposes of this study, direct participation in public consultation processes in ABS negotiations, even where opposed to the issuance of an ABS permit, are not considered to be ‘claims of misappropriation or unauthorized access,’ since these processes are designed to ensure that whatever access occurs is authorized, and to prevent misappropriation. However, requests for rescission of an ABS permission after it has been issued have been included in this study, as such requests are generally based on the allegation that the permission should not have been granted and that action taken under that permission is therefore misappropriation.

³⁵² Several industry representatives noted that this issue has arisen more commonly in claims that have not been publicized.

³⁵³ Information regarding the date of collection was not clear in several other public claims (Nuna Bean, Yellow Bean, Pozol, Hoodia, Cunani and Tipir), but suggested the possibility of pre-1992 collection and other activities.

³⁵⁴ A converse of this kind of claim has been suggested in another forum. In the implementation of the Convention on International Trade in Endangered Species of Fauna and Flora (CITES) (Washington, DC, 1973, entered into force, 1975), several countries have expressed concern that a user will interpret a CITES export permit or “introduction-from-the-sea certificate” (Articles III.2, III.5, IV.2, IV.6, V.2, and VI) to be a governmental permission to utilize the specimen, including its genetic resources. (See Proceedings of COPs 11 and 13, and of the IUCN/BMZ//TRAFFIC/UNEP Expert Workshop Promoting CITES-CBD Cooperation and Synergy, International Academy for Nature Conservation, Isle of Vilm, Germany, 20–24 April 2004).

³⁵⁵ In some instances, one who infringes a patent may be required to pay royalties and other penalties to the patent holder. However, rarely if ever is the holder of an invalidated patent required to pay in this way.

³⁵⁶ The minimal payment required for obtaining this amount of biological material cannot provide a commercial incentive for conservation and sustainable use as envisioned by the convention (Art. 11), nor can it equitably compensate the source country for the value obtained.

³⁵⁷ There remain some highly complex and delicate species that cannot be cultured *ex situ*. In some cases, this will mean that these species will need to be continually collected in large quantities, even when products are in commercial production. The control of these collecting

processes, like all collection or harvesting of natural resources, must be governed by natural resource management institutions and practices, and by sustainable use principles.

³⁵⁸ It should be noted that the landowner, community or national park agency still has a full right to control physical entry into their property, including requiring payment for this entry, in accordance with national law.

³⁵⁹ That is, with no intent to utilize their genetic resources.

³⁶⁰ Art. 15.2.

³⁶¹ Art. 1.

³⁶² Art. 15.7.

³⁶³ See UNEP/CBD/WG-ABS/3/5, section II. A few countries have adopted some level of measures applicable to users in their country, however these are countries that are primarily thought of as “source countries.” Id. A full analysis of substantive national ABS laws can be found in Cabrera, J. 2004. A Comparative Analysis on the Legislation and Practices on Access to Genetic Resources and Benefit Sharing (ABS): Critical Aspects for Implementation and Interpretation. IUCN, The ABS Project.

³⁶⁴ In recent discussions, representatives of several user countries have indicated their position that Article 15.7 requires only that the user country's law must allow foreign countries or citizens to bring lawsuits. See, e.g., Presentation of L. Hirsch at the ABS International Expert Workshop on Access to Genetic Resources and Benefit Sharing, (20–23 September 2005, Cape Town, co-hosted by Norway and South Africa).

³⁶⁵ In general, patent-related claims have been based on lack of “novelty” and “innovation,” two primary requirements for a valid patent. Both of these components would arguably be satisfied in a patent of a new variety developed through genetic manipulation.

³⁶⁶ The most compelling motivation arises in cases in which the patent-holder asserts his patent by charging or threatening to charge a royalty – insisting that farmers using the traditional variety which he has patented must pay him in the future, if they intend to continue to market the produce. It would have been impossible for these farmers to patent the variety themselves, as there was no innovation involved – the varieties such as basmati and jasmine rice, and several others mentioned in [Table 1](#) were already in general use in the manner described in the patent. Once patented there was no way to distinguish between the patented variety and the traditional varieties already being marketed. (These facts are based on the Yellow Bean (Enola Bean) patent case, and are the subject of a pending action for revocation of the US patent granted in the case).

³⁶⁷ This sentiment was echoed in detail by all industry representatives interviewed in the course of confidential interviews ([Table 2](#)).

³⁶⁸ In cases such as the extremophiles claim involving Kenya, the claimants have chosen to avoid this question, by focusing on whether the user had obtained the necessary permission to collect the biological specimens (which were taken from a protected area).

³⁶⁹ Similar phenomena have been seen in the field of corporate social responsibility (CSR), where companies that have made positive public commitments to promote CSR are more likely to be the targets of publicly asserted CSR complaints for small concerns, than are companies that have refused to consider CSR, even when the latter are charged with serious violations. See, e.g., Christiansen, A.C. 2002. “Beyond Petroleum: Can BP Deliver?” (FNI Report 6/2002, available online from FNI website at www.fni.no/publ/energy.html); Skjærseth, J.B. 2003. “Exxon Mobil: Tiger or Turtle on Social Responsibility?” (FNI Report 7/2003, available online from FNI website at www.fni.no/publ/energy.html).

³⁷⁰ As noted, most of the direct claims were resolved under patent law. The deciding body either concluded that the patent was invalid (due to lack of novelty or inventive step) or allowed it to stand. There is no legal authority under patent law to evaluate whether the patent holder's other actions (aside from filing his patent) were legal or not. Hence, misappropriation issues could not be decided in a patent claim.

³⁷¹ Presented in JBA/UNU Roundtable on ABS, 11 March 2005. Available in Japanese at www.meti.go.jp/policy/bio/index.html and soon to become available in English.

³⁷² Clause E.9(c), as noted at the beginning of this report.

³⁷³ Even where some interim decision or other result has been obtained, it is not clear from review of the literature, interviews of parties and other factors, whether additional action or results are expected.

³⁷⁴ Another factor that makes it difficult to gauge the benefits and impacts of the results of claims on ABS compliance is time. In general, with few claims having been formally asserted, and mostly in the slowest of judicial processes (patent agencies), the only results received to date have been very recent (by legal reckoning). Similarly, ABS is a process governed by legislation and contract law, both of which are relatively slow to change and in both the ultimate result of such changes are generally slow to be seen, given that contracts and other activities must pass through their entire legal existence before their impacts can be fairly evaluated.

³⁷⁵ This point is based on discussions of ABS issues in COP 7, including Working Group 1, and the ABS Contact Group meetings throughout that Conference. A review of recent literature will turn up numerous articles regarding the paucity of actual ABS-related claims.

³⁷⁶ An issue being addressed under CBD-COP Decision VII/19, at paragraph E.10.e.

³⁷⁷ Note that this table is based on descriptions and interviews. The authors had little ability to review actual documents relating to these claims. All information is provided to the best knowledge of the authors, with blanks indicating issues on which no information or conflicting information was found.

³⁷⁸ The letter inserted in this column refers to the points made in the available documentation of the claim. It is not clear whether other TK-related claims may have been asserted that were not identified in the particular documents available for review. In many instances, direct use of TK may be a primary assertion with GR uses not yet fully known.

