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DEFUSING DISCLOSURE IN PATENT APPLICATIONS

Strengthening legal certainty in the International Regime on Access to Genetic Resources and Benefit-Sharing and supporting WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

Information note by the Executive Secretary

1. The Executive Secretary is pleased to circulate herewith, for the information of participants in the tenth meeting of the Conference of the Parties, an information document entitled "Defusing Disclosure In Patent Applications: Strengthening legal certainty in the International Regime on Access to Genetic Resources and Benefit-Sharing and supporting WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore" submitted by the ESRC Centre for Economic and Social Aspects of Genomics (Cesagen), Lancaster University and the United Nations University Institute of Advanced Studies (UNU-IAS) as a contribution to agenda item 3 'International Regime on Access and Benefit-sharing'.

2. The document is being circulated in the form and language in which it was provided to the Secretariat.

* UNEP/CBD/COP/10/1.

DEFUSING DISCLOSURE IN PATENT APPLICATIONS:

Strengthening legal certainty in the International Regime on Access to Genetic Resources and Benefit-Sharing and supporting WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.[1]

ADVANCED DRAFT

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Executive Summary

Objective

This report provides analysis and factual data on ways forward for the successful introduction of a practical system for monitoring the utilisation of genetic resources and traditional knowledge. It suggests a resolution to a key issue blocking the creation of such a system. This resolution is based on 4 elements:

1. Acknowledging and analysing the current impasse between the Convention on Biological Diversity (CBD), the World Trade Organisation (WTO) and the World Intellectual Property Organisation (WIPO) on the disclosure of certain biodiversity information in patent applications (Section 1).

2. Analysing a useful precedent for a functional disclosure requirement using the Bayh-Dole provisions of the US Patent Act (Section 2).

3. Interrogating the patent system to see to what extent disclosure of countries of origin already takes place (Section 3).

4. Interrogating the patent system to explore disclosure issues with respect to indigenous and local communities and traditional knowledge (Section 4).

Conclusions

1. The relationship between CBD, WTO-TRIPS and WIPO on disclosure is dysfunctional.

2. Finding a way to defuse the issue of disclosure is the most likely way to lead to a functional relationship.

3. Analysis of experience with the Bayh-Dole disclosure statement for federally funded research under the US Patent Act demonstrates that disclosure provisions do not place an unnecessary burden on patent offices, researchers, inventors, or regulatory bodies funding research. Furthermore, a disclosure statement can be monitored and tracked without undue difficulty.

4. A similar requirement for a statement on access and benefit-sharing in patent applications would not place an unnecessary burden on patent offices, researchers, inventors, or regulatory bodies.

5. Global patent data is increasingly available in electronic form but the relative immaturity of access to, and the transparency of, global patent information makes monitoring and tracking of biodiversity and traditional knowledge more difficult than it should be. Tools exist to make the task easier but the further development of such tools should be encouraged to meet biodiversity information requirements in access and benefit-sharing.

6. The adoption of common practices in disclosure statements in patent applications would increase the traceability of the commercialization of genetic resources for the benefit of stakeholders and reduce the due diligence burden on entities seeking an economic interest in such patents.

7. Global tracking and monitoring of the utilisation of genetic resources is made possible through a disclosure statement. Tracking and monitoring is possible by searching global

patent databases using species names or common names but is more difficult than it should be. There is significant room for improvement in the clarity and form of existing disclosure of species and associated country names in patent applications.

8. An analysis of the experience of 18 countries with existing disclosure requirements shows that the basis for an international norm for disclosure already exists and that there is scope to improve access to, and transparency within, the patent system for the benefit of all stakeholders.

9. The use of traditional knowledge can be traced within the patent system, particularly when it sits within a written tradition. Traceability of the knowledge, innovations and practices of indigenous and local communities within the patent system would be improved if disclosure included the identity of the indigenous and local communities providing the knowledge.

10. Improved visibility of the authorized use of indigenous and local community traditional knowledge would enhance certainty for communities that their conditions for access and use of traditional knowledge and associated resources were being met. This would have the secondary benefit of making prior art searches by patent examiners easier.

Recommendations

1. Information about the source of genetic resources and associated traditional knowledge used to develop an invention should be included in a Statement on Access and Benefit-Sharing in the text of patent applications. That statement should include information on prior informed consent, mutually agreed terms and other relevant information. The obligation to disclose may be contained within mutually agreed terms (contracts), by provisions within biodiversity laws or by amendment of national patent law.

2. Efforts should be made to improve access to global patent data. This could be achieved through greater electronic access to the whole text of applications.

3. The continued development of patent information systems should be encouraged, particularly by the European Patent Office in its role as the global repository of patent data for public use and statistical purposes.

4. The patent system should improve the visibility of biodiversity through the use of species lists held in taxonomic databases including the Species 2000 & ITIS *Catalogue of Life* and the Global Biodiversity Information Facility (GBIF) and related regional and national portals and databases such as The Atlas of Living Australia.

5. Information on traditional knowledge used in the development of an invention should be accompanied by the correct identification of the community or communities concerned and prior informed consent and mutually agreed terms. The use of the *Ethnologue Catalogue* of global language names (in accordance with ISO 639-3) would contribute to certainty for indigenous and local communities.

6. The CBD and its ABS Protocol should provide guidance to the WIPO IGC on the minimum form and content of information to be disclosed for monitoring and tracking the commercialisation of genetic resources and associated traditional knowledge. Information provided should be retrievable by electronic information systems and coded on the front page of applications. This could be achieved by using standard two letter country codes and unique numeric identifiers inserted into the existing citation field in patent databases.

1. Introduction

Have you ever wondered why so little progress has been made on the issue of disclosure of biodiversity and regulatory information in patent applications? It is a key issue in current negotiations within no less than three international bodies, the Convention on Biological Diversity (CBD), The World Intellectual Property Organisation (WIPO) and the World Trade Organisation (WTO). Yet the absence of substantive progress asks the question: Why? For nearly a decade there has been keen discussion, international committees established, mandates given, meetings held, proposals put. But no concrete outcome results from all this effort. Why?

This paper seeks to answer that question and in doing so, to suggest a positive way forward enabling common objectives to be met and practical difficulties to be understood and resolved.

Authority to act:

On the face of it, the answer to the lack of progress on disclosure cannot be a lack of authority or political commitment by the governments of the world. The 2002 World Summit on Sustainable Development (WSSD) Plan of Implementation is quite explicit.[2] Countries agreed at paragraph 44 to:

> 44(n) - promote the implementation of the Bonn Guidelines through national action
>
> 44(o) – negotiate an International regime on ABS within the framework of the CBD
>
> 44(p) – successfully conclude the WIPO IGC process and Working Group on Article 8J of the CBD
>
> 44(q) – share technology benefits from the use of genetic resources
>
> 44(r) – promote discussion on the relationship between CBD and trade conventions as set out in the Doha Ministerial Declaration.

Disclosure of information in patent applications is relevant to each of these WSSD responsibilities.

These commitments were further embedded in the international system with the UN General Assembly's endorsement of the Plan the following year.[3] Eight years later, not a lot has changed. The international regime negotiations within the CBD are only now drawing to a conclusion, The WIPO Intergovernmental Committee (IGC), with its new mandate, has another 2 years to run and the Doha Round is stalled.

The CBD gave detailed guidance on the process for the negotiation of an international regime. This was decided by the Parties to the CBD in Decision COP VII24 D Annex. This sets out the mandate for the negotiations. Paragraph (d) identifies a series of elements to be considered. This includes:

> (xiv) Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights;

Clearly the problem lies not in the authority to consider (and resolve) the issue of disclosure of information in patent applications or in the international machinery established for the matter to be addressed. This leads us to conclude that the impediment to progress is more fundamental. Identifying that impediment and understanding it, it might then allow thought to be given to its removal or at least to reducing its impact.

Conventional arguments against changing the status quo

Critics of proposals to amend the international patent system to address disclosure of origin present two main arguments against taking action within the patent system. These arguments are seen by their proponents as validating the need for caution, and by others, as serving as a smoke screen for a lack of action to protect the status quo.

Firstly, it has been rightly pointed out that the CBD is a multilateral *environment* convention. They argue the CBD has neither the expertise nor authority to deliberate on intellectual property (IP) matters, particularly the operation of the patent system. Accordingly, the question of whether and what might be disclosed in a patent application should not be dealt with by the CBD. There is some truth in this assertion, in so far as the professional background of many delegates to the meetings of the Convention tends more to the biological sciences than to intellectual property law. The wider argument is however based on a false premise.

To assert that the CBD is solely an environment convent ignores the third objective of the Convention, i.e. benefit-sharing from natural resource use. This objective is economic and trade based.[4] The CBD is therefore a trade and environment treaty. More, not less, delegates with trade and economics backgrounds are needed to assist in its deliberations.

The advancement of national sovereignty over natural resources and obtaining a share in benefits deriving from its use is a legitimate trade and economic matter. Unsurprisingly, therefore, the Convention has a legitimate interest in the operation of the IP system as a means of crystallising value in inventions based on genetic resources and any related traditional knowledge. This being the case, the question becomes what is the appropriate way for the CBD to pursue that interest?

The second counter-argument questions the legitimacy of using the patent system to achieve non-IP related ends. The argument runs that, using the patent system to identify possible misappropriation of natural resources and as a means to demonstrate compliance with national access and benefit-sharing (ABS) laws is a wrongful use of the system with potentially serious consequences that have not been thought-through.

This raises the question: what is the purpose of the patent system? At its simplest, the patent system exists for the public benefit of supporting innovation through the disclosure of new and useful inventions in return for a time-limited right of monopoly use by the inventor. The grant of monopoly protection increases the rewards for innovation and accordingly encourages investment and risk-taking in research and development. While this philosophy may underlie the system, over the years its application has also served other purposes, including ironically, protection of national industry, prevention of technology transfer, and economic warfare. As recently as the immediate post Second World War period, the British government shaped patent law to minimise the costs of medicines to its National Health Service.[5] Without expressing any value judgements about national actions to meet varying public policy needs, the history of the patent system suggests that it has served multiple uses.

The second response to the pure use argument is that most proposals focus on the disclosure of relevant biodiversity related information in the patent application: they do not affect the criteria on which a patent is granted. Like the patent system itself, disclosure of information about the origins and circumstances of acquisition of genetic resources used in the development of an invention seeks to achieve its own public policy ends through transparency. That public policy end is the demonstration of compliance with applicable national ABS laws and the prevention of misappropriation of genetic resources covered by the CBD through transparency. This in turn assists with investment decisions by demonstrating the existence (or not) of legal certainty associated with the IP to be created. Moreover, it

allows parties with an interest in the commercialisation of their genetic resources to more easily track its use.

A triangular relationship

If the foregoing two arguments against disclosure of source in patent applications are capable of rebuttal, what then are the factors that have led to a lack of progress towards adoption? Proposal for disclosure of origin first emerged in the CBD but did not progress. In response to suggestions that intellectual property matters were best dealt with in WIPO, the WIPO General Assembly established the WIPO IGC to address this issue. A lack of progress in this forum in turn added pressure for action in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council. Discussions on the subject within the TRIPS Council over several years have also not resolved the issue.

We contend that, in essence, the parallel pursuit of the resolution of the issue of disclosure in CBD, WIPO and the WTO TRIPS Council has placed the three in tension, that this tension creates a dysfunctional dynamic and results in a policy development blockage that is exploited for other ends. This dynamic can be described in the following circular terms: A lack of progress in the WIPO IGC is used to justify action in the CBD. A lack of progress in the WIPO IGC is also used to justify action in TRIPS. A lack of progress in TRIPS is used to justify action in the CBD and so on. In each of these fora, other issues are in play and disclosure, as an issue, becomes a bargaining chip in a greater game. For example, progress might be made contingent on resolving market access issues or advancing a line on Geographical Indications or may simply serve a means of seeking delay while domestic ABS policy issues are debated.

This is an unhealthy and wasteful dynamic. Moreover it has other disturbing consequences. Firstly, it fosters distrust between parties making the resolution of conflicting views more difficult and creates frustration. Secondly, frustration leads to positional bargaining. This manifests itself in claims that a party knows, or should know, are unacceptable to others and therefore become a bargaining chip. It allows claims to be advanced that represent overreach, i.e. that are wrong, exceed the authority of the institutional body concerned or are unachievable. An example of this would be a claim in the CBD that the basic criteria for patentability should be amended for inventions based on genetic resources to add additional grant criteria relating to evidence of prior informed consent (PIC) and mutually agreed terms (MAT). Such a claim would be seen as interfering with WIPO's mandate and would be unacceptable to many parties in the CBD.

The descent into positional bargaining has other consequences. Proposals offering possible solutions are inadequately considered or are simply rejected. An example of this is the Swiss proposal to enable countries to stipulate what should be required in patent applications without risk of falling foul of the interaction between the Patent Law Treaty (PLT) and the Patent Cooperation Treaty (PCT)[6]. Switzerland proposed in the PCT an amendment of PCT Rule 4.17bis.1 that would have allowed countries to establish a disclosure requirement in patent applications and conform to the requirements of the PLT. This proposal was rejected almost out hand by some delegations. The only compromise offered was deferral of consideration. It may be that in the view of some developing countries, the proposal for disclosure of source did not go far enough compared with existing measures (i.e. Andean Community Decisions 486 and 391). However, the policy content of the proposal i.e. to tell what you knew, or did not know, in a patent application is not new, insofar as it reflected the basis of the EU position on disclosure in the TRIPS Council in 2000 and was in turn supported in-principle, by some other developed countries. The expanded concept of source that has

recently been advanced by Switzerland may go some way to bridging the gap and merits wider discussion (see Box).

Disclosure of Origin: Key Issues

A growing number of countries and regions have proposed or adopted measures for the disclosure of origin or source. (see Section Three). These proposals and adopted measures involve four main issues.

1. **Origin and Source:**

Disclosure of the country of *origin* of the genetic resources and the knowledge, innovations and practices of indigenous peoples and local communities ("traditional knowledge") utilised within patent applications is intended to meet the needs of developing countries. Disclosure of the *source* of genetic resources and TK refers to the sourcing of GR and TK from commercial suppliers, public collections, or countries where material is available. A related concept is to disclose the legal provenance of TK and GRs

A number of proposals seek to combine these concepts in an *expanded understanding of the concept of source*. A good example is the Swiss Patent Act of 2008 where: "The generic term source should be understood in its broadest sense, covering any type of provenance or origin". This includes: governments; the country of origin; providing countries; the geographic origin of resources under recital 27 of the European Biotechnology Directive; the Multilateral System under the Plant Treaty; natural or legal persons; indigenous and local communities; *ex situ* collections, and scientific publications and databases to reflect a possible cascade of sources (WIPO/GRTKF/IC/16/INF/14). This reflects a growing willingness to accommodate the range of possibilities for the disclosure of biodiversity and traditional knowledge within patent applications.

2. **Evidence of PIC and MAT:**

A number of proposals link disclosure with evidence of compliance with Prior Informed Consent and the existence of Mutually Agreed Terms. An international certificate system has been proposed to meet these requirements. We propose that a Statement on Access and Benefit-Sharing could be required within patent applications and include references to contract numbers, a certificate, permits or licences. This approach would conform with the Patent Law Treaty (PLT) and be consistent with the TRIPS Agreement.

3. **Direct or Indirect Use:**

A distinction may be made between direct and indirect uses of genetic resources and traditional knowledge as the "trigger" for disclosure. This focuses attention on inventions that immediately and directly use genetic resources or traditional knowledge. This limits the scope of the disclosure measure. In practice, determining whether a species or its components and traditional knowledge are directly involved can be resolved through claims analysis and case by case analysis of examples and references. Enhanced disclosure for biodiversity would support such analysis and raise the profile of biodiversity and traditional knowledge within the patent system.

4. **Consequences of Non-Compliance:**

The consequences of a failure to disclose focus on whether disclosure should have impacts within or outside patent law. In some cases disclosure is voluntary and does not affect standard patentability criteria. In the case of disclosure of origin a number of countries and the European Union have proposed that failure to disclosure and to remedy the absence of disclosure should lead to no further processing or rejection of applications. Outside of patent law fines or other criminal sanctions may be imposed where a court finds evidence for an intentional or misleading declaration of origin. In the United States under the Bayh-Dole Act a failure to disclose inventions arising from federal funding and to record federal funding and government interest in patent applications may result in transfer of patent title to the federal government. In addition, in certain circumstances, federal agencies may exercise 'march in' rights on inventions arising from federal support.

The Sleeping Issue

When enough countries, or enough participants in an economic market, adopt a rule or practice that rule or practice becomes normative. This is the basis of international customary law. While a number of countries in Europe have introduced, or are introducing, national disclosure options or requirements, this is not yet sufficient to have such an affect. However, when we add the requirements introduced by India, China, South Africa and those contained in Brazil's new draft ABS law a new situation emerges.[7] The more valuable an invention is, the more likely it will be patented internationally in markets that require some form of disclosure. Thus high value patents based on genetic resources are more likely to be subject to national disclosure requirements. It follows, therefore, that high value patents based on genetic resources and any associated traditional knowledge are, or are about to be, subject to disclosure. Meeting any instance of such a requirement in any one jurisdiction means that the fact and content of disclosure is then generally known. As we will demonstrate, disclosure can then be tracked worldwide. This has significant implications and is generally not acknowledged in debates within the CBD.

Defusing the tension and returning to effective consideration: a Strategy

Having asserted that an unhealthy dynamic exists around this issue and in the principal fora in which it is played out and having given some examples of its consequences, we now turn to a strategy for its resolution. The first step is to break this dynamic.

Since the dynamic is sustained by an absence of effective action, if that absence is filled by effective action in any one area, then the whole dynamic evaporates. The logical place for this to happen is within the CBD.

Underlying the formal communications between the CBD and WIPO by the COP is the recognition that the conventions must operate in a mutually supportive manner. Any action within the CBD must therefore not enter into the responsibilities of WIPO and its family of IP conventions nor be inconsistent with TRIPS obligations.

This is not difficult. It can be done, and indeed, the revised Draft Protocol annexed to the final Report of the Ninth Meeting of the Ad-Hoc Open Ended Working Group on Access and Benefit-Sharing contains relevant text where it says:

ARTICLE 13

MONITORING[, TRACKING] AND REPORTING THE [UTILIZATION] OF GENETIC RESOURCES [AND ASSOCIATED TRADITIONAL KNOWLEDGE]

1. Parties shall take measures, as appropriate, [to enhance transparency about, and] to monitor[, track and report] the [utilization] of genetic resources [, its derivatives and associated traditional knowledge] to support [compliance][.] inter alia, [with the requirement to obtain prior informed consent and establish mutually agreed terms] [prior informed consent requirements and mutually agreed terms] [under Article 12(1)]. Such measures [could][shall] include:

    (a) The identification and establishment of check points[[, which may include:][, including:]

    (iv) [Intellectual property examination][Patent and plant variety] offices; and

> [The [mandatory] disclosure requirement shall be met by providing [bona fide] evidence that a [permit or] certificate was granted [at the time of access] in accordance with [Article 5, paragraph 2 (d)]][prior informed consent and mutually agreed terms as provided by national legislation];]

The first thing to note about this formulation despite the inclusion of many brackets is that it does not amend the existing patent system in any way. It does go some way to ensuring that lawfully obtained genetic material is disclosed, transparently and globally, through a variety of means including through the patent system and its associated electronic patent library systems. Accordingly the draft provision seeks to introduce and demonstrate the existence of primary legal certainty: permanently and at low cost to any and all interested parties.

Such action creates a comparative market value advantage for inventions based on lawfully obtained material and is consequently a powerful step in compliance.

The second thing to say about this step is that there is a long-standing precedent for this approach within the patent world. Formal, legislated disclosure measures were introduced in the United States by the 1980 Bayh-Dole Act as an amendment to United States patent law (USC 35). The Bayh-Dole Act requires that recipients of federal funding must disclose the source of federal funding in any subsequent patent applications and meet federal agency reporting requirements. This disclosure requirement is supported by guidance to patent applicants on the appropriate placement of a *Statement Regarding Federally Sponsored Research or Development* and related model clauses within the description section of patent applications. Furthermore, this requirement also allows the US government to track the commercialisation of federally funded research and to readily and objectively identify where research expenditure is most productive. This provision does not appear to have given rise to any burden of litigation. We will use the Bayh-Dole disclosure requirement as a proxy for a practical disclosure measure on access and benefit-sharing in relation to the patent system.

Thirdly, it is important to recall that the fundamental long term purpose of the patent system is the disclosure of new and useful inventions to the public for wider use and dissemination. An exclusive focus on the rights provided by patents, and the potential impacts of particular proposals on patent applicants, obscures this fundamental purpose. In recent submissions to the WIPO IGC it has become clear that many countries view disclosure of the source of genetic resources or traditional knowledge in light of the well established substantive requirement for adequacy of disclosure as a condition of patentability. That is, an applicant should disclose sufficient information for others to reproduce the invention. This forms a key part of the teaching function of the patent system and is central to the long term legitimacy of the patent system. Disclosure measures may therefore also have a useful role to play in addressing the crisis of quality that is confronting the major patent offices and meeting the terms of the 'bargain' with the public involved in the provision of temporary monopoly rights in return for disclosing new and useful inventions.

Objections have been raised to disclosure requirements on the grounds of a lack of consistency with international law. However, it is increasingly clear that national requirements for CBD disclosure in patent applications are fully consistent with the flexibilities and substantive provisions in existing international law treaties.[8] In practice, such requirements should be understood as permissible, substantive conditions on entitlement to apply for patent rights and to own patents, designed to prevent misappropriation of genetic resources or traditional knowledge.[9]

This conclusion is supported by recent developments in international patent law. Thus, the Patent Law Treaty (PLT) entered into force in 2005 and aims to harmonise certain formal elements of patent procedure. Article 14 of the PLT is concerned with Regulations under the PLT including recordation of a license or security interest (Art. 14.1(b)(ii)). Rule 17 of the PLT Regulations establishes that where applicable law requires the recordation of a license a Contracting Party may require that this contains "information relating to any government interest by that Contracting Party" and licensing terms (Rule. 17.1(b)(iii)).[10] A model form is provided for the purpose of providing such information (Rule 17). This demonstrates that significant flexibility exists within the patent system to allow states to address CBD disclosure needs.

In this report we will propose three key measures to be undertaken in the context of the international regime on access to genetic resources and benefit-sharing. These measures focus on transparency, certainty and access to information. They are to:

1. Improve the clarity and form of disclosure of the source of genetic resources and traditional knowledge in patent applications;
2. Include a statement on access and benefit-sharing in the text of patent applications with information required by provider countries such as contract numbers and other relevant information;
3. Improve access to, and the visibility of, biodiversity related information in patent information databases, notably by the European Patent Office as the main repository for the world's patent information.

The first of these measures addresses the need to improve certainty for provider countries and indigenous communities about whether genetic resources and traditional knowledge are the subject of applications for patent rights. This measure would also improve the visibility of the utilisation of biodiversity and traditional knowledge within the global patent system.

The second of these measures would improve certainty for provider countries and applicants and indigenous and local communities that the genetic resources and any associated traditional knowledge had been legitimately acquired under the terms of an access and benefit-sharing agreement.

The third measure focuses on improving certainty by facilitating monitoring and tracking of resource use through existing patent information systems and, in particular, the central patent documentation repository operated by the European Patent Office.[11] In practical terms much could be achieved through the use of existing patent database systems.

What then would be the effects of taking such basic actions under the CBD? It would remove the justification for taking comprehensive action within TRIPS and WIPO on the grounds that disclosure is an IP issue and the CBD would or should not take action on the issue. This would then allow the WIPO IGC to act more effectively within its new mandate. Instead of competing with CBD or TRIPS it would be free to focus on compliance supporting measures to provide support for the implementation of obligations established by the CBD and its forthcoming Protocol as part of its consideration of the content of mutually agreed terms.

The WIPO IGC could also more clearly see its role as working to better harmonise existing and future disclosure requirements in national patent legislation. This would entail the application of its specialist expertise to secure productive and practical outcomes. This is especially pertinent when considering the increasing range and significance of national patent

laws providing for disclosure of information about the origin and source of genetic resources and any associated traditional knowledge used in inventions.

Finally, by taking immediate action within the CBD or its forthcoming Protocol the CBD is well placed to take into account the primacy of national sovereignty over genetic resources and consider that while patents are an option in the commercialisation process, providers and users have the flexibility to choose other alternatives - if that suits their mutual interests better. For example in the nutraceutical and cosmetic fields greater benefits may flow from going down the trade-secret path than patenting. In other cases, "open source" or "commons" models or similar emerging alternatives may better serve research and development priorities for conservation, sustainable use or other needs.

Report Structure:

This report has adopted an empirical approach to the problem of disclosure of genetic resources and traditional knowledge in patent applications. The research provided in the report is based on a combination of research using patent databases, text mining and analytical tools at the forefront of modern patent analytics. The report is divided into three main sections.

Section 2 uses the long established requirement in the United States for the disclosure of federal funding in patent applications as a proxy for possible disclosure measures for access to genetic resources and benefit-sharing. We examine the structure and key provisions of the 1980 Bayh-Dole Act of relevance to debates on access and benefit-sharing, including the nature of the disclosure requirement and monitoring, indicators and reporting requirements. We then examine the practical challenges involved in implementing and monitoring this requirement to identify lessons for the development of access and benefit-sharing arrangements. Finally, in that section, we provide an empirical demonstration that a disclosure statement in the text of patent applications can be tracked around the world and used to identify species appearing in patent claims.

Section 3 reviews the status of disclosure of country names within the existing patent system including countries that have adopted enhanced disclosure measures. The review reveals that references to country names are a routine feature of patent applications including applications involving biodiversity and traditional knowledge. However, country names may appear for a variety of reasons and interrogating references to country names and species names involves significant challenges. A review of patent data for countries that have adopted enhanced disclosure measures suggests that patent applicants will rapidly adjust to requirements to name the origins and sources of materials referenced in patent applications. It is noted that patent applications frequently involve references to more than one country and more than one species. We argue that the problem is not so much disclosure *per se* but that the clarity and form of existing disclosure requires improvement.

Section 4 provides an exploratory analysis of disclosure in relation to indigenous peoples and traditional knowledge. The review reveals similar issues to those exposed in analysis of country names in patent documents. However, the diversity of uses of terms that may be used to describe indigenous peoples and local communities poses additional challenges. The analysis suggests that certainty could be improved for indigenous peoples and local communities through the use of established indexes of languages such as the *Ethnologue Catalogue* to identify patent activity involving indigenous peoples and traditional knowledge.

We also propose that relevant information on indigenous peoples and local communities should be included in a disclosure statement on access and benefit-sharing.

2. A Proxy Model for Disclosure: The Bayh-Dole Act

One challenge in debate on access to genetic resources and benefit-sharing and patent disclosure is a lack of working models to serve as a proxy. In this section we consider the insights that can be gained from analysis of a long-standing requirement for disclosure of federal funding in patent applications in the United States under the 1980 Bayh-Dole Act. We focus in particular on a requirement to include a Statement on Federally Sponsored Research and Development in the description section of patent applications.

We begin by providing an overview of the Bayh-Dole Act and its key provisions with respect to allocation of government rights, licensing, disclosure and reporting. We then focus on the challenges that confronted US federal agencies in implementing these provisions and the wider link between disclosure and national indicators on research and development. The main body of the discussion is based on experiments to track the Bayh-Dole disclosure requirement for biodiversity related patents from the United States patent system into the global patent system. These experiments demonstrate that it is possible to track a disclosure statement for biodiversity patents around the world. This includes identification of species referenced in the claims of patents funded by the United States government. We conclude that a Bayh-Dole style disclosure statement provides a functional working model with minimal implications for the patent system that could readily be adapted for access and benefit-sharing. Building on experience with Bayh-Dole disclosure we provide recommendations on ways forward in adapting the proxy model to meet the needs of access and benefit-sharing under the CBD.

2.1 The Bayh-Dole Act:

The Bayh-Dole Act (University and Small Business Patent Procedures Act) was adopted by the United States Congress in 1980. Bayh-Dole was adopted against a background of concern that the results of federally funded research were not being adequately commercialised to the detriment of the public and the economy of the United States. As recent commentators have observed:

> "Fundamentally, Bayh-Dole shifted the incentive structure that governed the research and development path of federally funded inventions by allowing institutions to own inventions resulting from federally sponsored research and to exclusively license those inventions. The Act also requires the institution to establish patent policies for its employees, to actively seek patent protection and to encourage the development of their inventions."[12]

The key features of Bayh-Dole Act are:

1. Universities, small businesses and non-profits may elect to obtain patent rights (title) to inventions arising from federally funded research within the United States and elsewhere in the world;
2. If recipients of federal funding elect not to pursue title the federal agency providing the funding may pursue title;
3. The federal agency, on behalf of the US government, retains certain rights in the inventions, including a non-exclusive royalty free licence to the invention anywhere in the world and the right to "march in" for abuse of patents;
4. Applicants are required to include clauses in patent applications setting out the government interest and to inform the federal agency of the pursuit of patent rights.

Applicants are further required to report on the maintenance, abandonment of patents or opposition to patents in any country.

Bayh-Dole was originally targeted at technology transfer from the government to universities, small businesses and non-profits. However, the provisions of Bayh-Dole were subsequently extended to large businesses by Ronald Reagan under Executive Order 12591. In separate legislation in 1980 the Stevenson-Wydler Technology Innovation Act (12 USC 3710a) promoted technology transfer from Federal Laboratories through the use of Cooperative Research and Development Agreements (CRADAs). CRADAs have featured in debates on access and benefit-sharing with respect to Yellowstone National Park.[13] These Acts were followed in the year 2000 by the Technology Transfer Commercialization Act that sought to promote technology transfer from over 700 federal laboratories to industry through the simplification of bureaucratic barriers and licensing of federally owned inventions.[14] This section is primarily concerned with the Bayh-Dole Act. However, it will also at times present data from this related legislation.

Bayh-Dole has been widely copied in developed countries as part of a process characterised by the OECD as "Turning Science into Business".[15] This process involves legislative reform to assert institutional ownership of intellectual property generated by employees, the creation of technology transfer offices within universities, the development of patent portfolios and the establishment of spin-off companies. Such measures have been widely adopted in European Countries and similar measures have been adopted in India and South Africa.[16]

In 2002 *The Economist* described Bayh-Dole as "Possibly the most inspired piece of legislation to be enacted in America over past half-century..."[17] In particular, Bayh-Dole is largely held responsible for the rapid expansion of university patent activity in the period following its adoption and the establishment of emerging bioknowledge science led sectors such as the biotechnology industry. However, Bayh-Dole has also been a focus of criticism with respect to five main issues:

1. Restricting the research exemption for the use of intellectual property without infringement as a result of transforming universities into commercial entities and muddying the distinction between non-commercial and commercial research;[18]
2. Restrictions on access to basic research tools and enabling technologies in biology, such as Taq DNA polymerase originating from *Thermus aquaticus* in Yellowstone National Park, and the impacts of licensing fees on the costs of basic research for researchers and taxpayers.[19]
3. 'Anticommons' effects from the increasing fragmentation of intellectual property holdings arising from government funded research, the overvaluation of patent value by patent holders leading to rejection of reasonable offers and fear of infringement;[20]
4. Chilling effects on the development of, and access to, publicly funded technologies to serve humanitarian purposes in both the United States and in developing countries;[21]
5. The implications of the adoption of a 1980s patent led model of innovation for science and innovation in the 21st Century in developing countries;[22]

These criticisms arise from a perception that in practice Bayh-Dole has exclusively promoted a patent based model of ownership at the expense of other possibilities. In response members of the scientific community have increasingly begun to promote non-exclusive "scientific commons" and "open source" approaches to research and development.

Debates on access and benefit-sharing have paid limited attention to the Bayh-Dole Act and its wider implications. In practice, many of the controversies in access and benefit-sharing, such as the commercialisation of university research, can be traced to the model of innovation promoted by the Bayh-Dole Act. Our focus in this discussion is on the lessons that can be learned from experience with the Bayh-Dole disclosure requirement. However, we should not lose sight of underlying debates on the purposes of disclosure. In particular, there is a need to keep in mind the consequences that may flow from disclosure and wider practices, notably licensing, to which disclosure is linked. We will highlight these issues at various points in this analysis.

Bayh-Dole and United States Patent Law:

Bayh-Dole was approved by Congress as an amendment to US Patent Law (USC 35). The provisions of the Bayh-Dole Act, including a disclosure requirement, are set out in Chapter 18 of the United States Patent Law (USC 35) entitled *Patent Rights in Inventions made with Federal Assistance.*[23]

Chapter 18 sets out a range of provisions covering issues such as Disposition of Rights (§202), March-in rights (§203), confidentiality (§205), Uniform clauses and regulations (§206), domestic and foreign protection (§207), Licensing (§208 & §209), and anti-trust law (§211) among other topics.[24] We will address some of these major sections below. However, it is useful to note that the positioning of the Bayh-Dole Act and its disclosure requirement within US patent law does not appear to have an impact on the standard criteria for patentability (that inventions be new, involve an inventive step and be useful).

The distinction between the provisions of Bayh-Dole and the standard criteria for patentability was clarified in a 2004 dispute between the University of Rochester against Searle, Monsanto and Pfizer concerning COX-2 inhibitors. In this dispute the US Court of Appeals for the Federal Circuit concurred with an *amicus curiae* filing by Eli Lilly to the effect that: "...no connection exists between the Bayh-Dole Act and the legal standards that courts employ to assess patentability."[25]

This is significant for debates on access and benefit-sharing because it suggests that ABS disclosure measures need not have an impact on the basic requirements of patentability even where they form part of patent law. However, as we will see, Bayh-Dole does provide for a degree of government control over patent applications including through reservation of some rights, transfer of title and "march in" rights. We now turn to the key provisions of the Act.

Disposition of Rights:

Section §202 establishes that non-profit organizations or small businesses receiving federal funds (contractors) may elect to retain title to an invention except where a funding agency determines otherwise. Specifically, the US government may retain title if the contractor is under the control of a foreign government, where national security is involved, or in "exceptional circumstances" where retention of title would better serve the objectives of the Act.

This section also establishes that a contractor should disclose an invention to the relevant federal agency within a reasonable time period and pursue title within the statutory time period. If the contractor fails to comply the right to pursue title reverts to the government (§202 (c)(1)). Federal agencies are also empowered to require periodic reporting with

provision made for the protection of confidential commercial and financial information (§202 (c)(5)). [26]

In a provision of possible relevance for access and benefit-sharing the government limits certain aspects of the rights available to patent holders through a requirement for a non-exclusive worldwide license:

> §202 (c) (4) "With respect to any invention in which the contractor elects rights, *the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world*..." [27] (emphasis added)

The disclosure requirement takes the form of an obligation to disclosure the source of federal funding and retention of certain rights in the text of a patent application as follows:

> §202 (c) (6) "*An obligation* on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, *to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention*." (emphasis added)

With respect to assignment of rights by a recipient of federal funding, specific provisions are included in the case of non-profit organisations that require permission from the Federal Agency. These organisations are also required to share royalties with inventors, and use royalties "for the support of scientific research and education" (§202 (c)(7)).

March-In Rights:

Section §203 sets out March-in rights that may allow a Federal Agency to require a contractor or assignee "to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances" (§203 (a)). If the contractor refuses to comply the Federal Agency is empowered to grant such a license itself in circumstances where:

1. A contractor will not achieve practical application of the invention;
2. Action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
3. Action is necessary to meet requirements for public use;
4. Action is necessary where agreement has not been reached on the preference for US industry under section §204 of USC 35, 18.[28]

The "march in" provisions are the subject to an appeals procedure. In practice, while the march in provisions of Bayh-Dole are widely known as the 'stick' accompanying the 'carrot' of access to rights over federally funded research outcomes, the stick has not been used (see below).

Domestic and Foreign Protection:

Section §207 empowers federal agencies to:

(1) "apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest;
(2) grant nonexclusive, exclusive, or partially exclusive licenses under federally owned inventions, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of chapter 29 of this title as determined appropriate in the public interest;"[29]

Finally, the Secretary of Commerce is authorised to "assist Federal agencies in seeking protection and maintaining inventions in foreign countries, including the payment of fees and costs" and advise on areas of science and technology with potential for commercial utilization.

Licensing:

Section §208 of Chapter 18 authorizes the Secretary of Commerce to develop regulations on the terms and conditions for the licensing of federally owned inventions "on a nonexclusive, partially exclusive or exclusive basis". The preference for exclusive licensing that has emerged at the expense of nonexclusive or partially exclusive licensing has been a particular focus of criticism and proposals for reform (see below).

Section §209 empowers federal agencies to grant exclusive or partially exclusive licenses where such grants will promote capital investment in the invention, utilization by the public and will not lessen competition or violate antitrust law. Section §209 (d) reiterates that licensing provisions shall retain "*a nontransferable, irrevocable, paid-up license for any Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States*" (§209 (d)(1)). It also requires periodic reporting on the utilization of the invention to determine whether the license is being complied with while establishing that commercial or confidential information shall not be the subject of disclosure (§209 (d)(2)).[30] Federal agencies are empowered to terminate the license in whole or in part if the practical application purposes of the license are not being achieved, for breach of license terms, where the requirement for public use is not being met, or in cases of violation of Federal antitrust laws.

§209 (e) establishes that: "No exclusive or partially exclusive license may be granted... unless public notice of the intention to grant an exclusive or partially exclusive license on a federally owned invention has been provided". This provision includes a fifteen day notice period and review of comments received. [31] The requirement to issue a public notice of an intention to grant a license is potentially important in the context of debates on access and benefit-sharing and a certificate system, where public notice would allow the public and interested parties to review and make comments on a certificate or license.

Finally, §209(f) requires that a person seeking a license to a federally owned invention must provide a plan for the development or marketing of the invention that will be treated as confidential and not subject to disclosure.

Implementing Regulations:

The provisions of the Bayh-Dole Act are implemented within the *Code of Federal Regulations 37* (CFR 37) Chapter 4 on *Patents, Trademarks, and Copyrights Part 401* concerning *Rights to Inventions made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts and Cooperative Agreements.*

Licenses and Invention Disclosure:

Of particular interest for access and benefit-sharing are the standard patent rights clauses.[32] These clauses establish that:

"...the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world" (401.14 (a) subpara (b)). (emphasis added)

The Regulations also set out the requirements for disclosure to federal agencies under 401.14 (c) *Invention Disclosure, Election of Title and Filing of Patent Application by Contractor*:

(1) The contractor will disclose each subject invention to the Federal Agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the Contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the contractor.

Consequences of a Failure to Comply:

The consequences of a failure to comply available to agencies include transfer of a recipient's rights to an invention to the government under 401.14(d) specifying Conditions When the Government May Obtain Title. "The contractor will convey to the Federal agency, upon written request, title to any subject invention --

(1) If the contractor fails to disclose or elect title to the subject invention within the times specified in (c), above, or elects not to retain title; provided that the agency may only request title within 60 days after learning of the failure of the contractor to disclose or elect within the specified times.
(2) In those countries in which the contractor fails to file patent applications within the times specified in (c) above; provided, however, that if the contractor has filed a patent application in a country after the times specified in (c) above, but prior to its receipt of the written request of the Federal agency, the contractor shall continue to retain title in that country.

(3) In any country in which the contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention."

As noted by the Government Accountability Office in 2009 "Failure by the contractor to disclose the invention, elect title to it, or file a patent application within the times specified, or failure to follow through with the patent application process, allows the relevant federal agency to obtain ownership of the invention" (see below).[33]

Standard Disclosure Statement:

Finally, under 401.14 (f) Contractor Action to Protect the Government's Interest a standard clause is required as follows:

(4) The contractor agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, "*This invention was made with government support* under (identify the contract) awarded by (identify the Federal agency). The *government has certain rights* in the invention." (401.14 a, subpara (f)(4), emphasis added)

As will be seen below, in practice use of this phrasing is not uniform, making tracking of disclosure of government interest challenging.

Patent Office Rules and Guidance to Applicants:

The *Consolidated Patent Rules* under 37 CFR Part 1 regarding Rules of Practice in Patent Cases set out the requirements for disclosure from patent applicants in the structure of applications for plant patents (1.163) and utility (industrial) patents (1.77).[34]

1.163 is concerned with "Specification and arrangement of application elements in a plant application". Under Plant Patents (a form of plant variety protection) an applicant is required to list information in the following order within the specification.

(1) Title of the invention, which may include an introductory portion stating the name, citizenship, and residence of the applicant.
(2) Cross-reference to related applications (unless included in the application data sheet).
(3) Statement regarding federally sponsored research or development.
(4) Latin name of the genus and species of the plant claimed.
(5) Variety denomination.
(6) Background of the invention.
(7) Brief summary of the invention.
(8) Brief description of the drawing.
(9) Detailed botanical description.
(10) A single claim.
(11) Abstract of the disclosure.

In the case of utility (industrial) patents applicants are required to provide the following information under "Arrangement of application elements" (1.77 (b)). The specification should include the following sections in order:

(1) Title of the invention, which may be accompanied by an introductory portion stating the name, citizenship, and residence of the applicant (unless included in the application data sheet).
(2) Cross-reference to related applications (unless included in the application data sheet).
(3) Statement regarding federally sponsored research or development.
(4) The names of the parties to a joint research agreement.
(5) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on a compact disc and an incorporation-by-reference of the material on the compact disc (see § 1.52(e)(5)). The total number of compact discs including duplicates and the files on each compact disc shall be specified.
(12) "Sequence Listing," if on paper (see 1.821 through 1.825)

As this makes clear, the Bayh-Dole Act combines a requirement for recipients of federal funding to report to the funding agency on patent activity while the patent system requires applicants to include a statement regarding federally sponsored research or development within the description section of patent applications.

In our view this combination of provisions and measures could go a long way to meeting a potential disclosure requirement as part of access and benefit-sharing arrangements. We now turn to analysis of practical experience with implementation.

2.2. Experience with Implementation:

While the Bayh-Dole Act came into force in the 1980s it appears that it was not until the late 1990s that serious questions were raised about the extent to which the disclosure and reporting requirements were being met. [35]

A 1999 report by the Government Accounting Office to the Senate Judiciary Committee engaged in a review of available data from the USPTO, federal funding agencies and selected contractors involving more than 2,000 patents from 1997 that appeared to be the result of federal funding.[36] They also examined the reporting of inventions for National Institutes of Health (NIH) grants and information from agencies on how the government used royalty free licenses.

The review found that: "Federal agencies and their contractors and grantees are not complying with provisions on the disclosure, reporting, retention, and licensing of federally sponsored inventions..." under the regulations.[37] They also found that databases recording government royalty free licenses were "inaccurate, incomplete, and inconsistent and that some inventions are not being recorded at all. As a result, the government is not always aware of federally sponsored inventions to which it has royalty-free rights."[38]

The review of records for 2,000 patents issued in 1997 found that "official records on federally sponsored inventions - PTO's patent database and Government register - were in agreement only about 6 percent of the time".[39] They were unable to resolve many of the anomalies in follow up work and "identified other inventions that had not been reported at all."[40] The databases used to record information (including card index files) were difficult to use and cross-match while the reporting requirements were "often redundant and complicated".[41]

In reviewing the patent data they found that it was sometimes difficult to identify the agency involved, because only the government or wider department was referenced in the patent rather than the specific funding agency. In addition, on some occasions no contract or grant number was cited that could be referenced to an agency.

The main recommendation of the report was the streamlining of reporting. In response agencies began to take measures to improve compliance and monitoring, principally through the establishment of the iEdison (Interagency Edison) database by the National Institute of Health as an extramural invention and tracking and management system involving online reporting by agencies and grant recipients.[42] This system is now used by multiple agencies including the Department of Defence and the Department of Energy. For grantees it provides access to electronic forms, notably online entry of patent information, frequently asked questions and an online tutorial system to assist grantees. [43]

In 2000 Congress passed the Technology Transfer Commercialization Act of 2000 that sought to promote industry friendly technology transfer between the network of 700 federal laboratories and industry including, in part, through "removing bureaucratic barriers and for simplifying the granting of licenses for inventions that are now in the Federal Government's patent portfolio".[44] In 2002 the General Accounting Office reported that federal agencies had taken some steps to improve reporting requirements for federally funded research but that duplication remained.[45]

In July 2009, the latest report available, the renamed Government Accountability Office provided a final report focusing on the use of march-in proceedings under Bayh-Dole at the four federal agencies accounting for 89% of federal research and development spending in fiscal year 2006.[46]

With regard to the monitoring of compliance, the report found that: "while they monitor contractor's compliance with reporting requirements, their agencies do not have ongoing efforts to identify potential candidates for march-in proceedings from the wide array of federally funded inventions."[47] Instead agencies relied on public and private sources of information, interest groups and potential competitors as well as participants in science and technology markets to raise issues of possible concern. Specifically, agency officials consulted expressed the view that: "relying on the public for information is a more efficient and effective mechanism for tracking federally funded inventions, which would otherwise require federal agencies to expend significant additional resources to monitor a large volume of federally funded inventions for possible situations that might lead to march-in proceedings".[48]

In an observation of relevance to access and benefit-sharing the long periods of time involved in commercialization were seen as a barrier to active monitoring. Agencies such as the National Institutes of Health (NIH) are also confronted by the scale of their operations. Thus, in 2008 NIH "provided 50,980 awards, worth about $21 billion, to 2,606 institutions". Furthermore, active monitoring would be complicated by the fact that a single invention might result in multiple licensing agreements for different uses i.e. a technology could be licensed for eye cancer and the same technology could be separately licensed for liver cancer.[49] In our view this exposes a need to be able to operate at scale and to address follow on innovation where simplicity in the measures taken is likely to be central to success.

The report found that march-in proceedings had not been conducted in the period since Bayh-Dole was enacted. However, the threat of march-in proceedings was regarded as useful

leverage by three of the four agencies. Four key disincentives to the use of march-in rights emerged in the report from the perspective of federal agencies:

1. The potential "chilling effect" on investors and some researchers in federal research efforts from the threat of march in proceedings;
2. The march-in procedure is lengthy and "could be unworkable in an emergency or other time-critical situation."[50]
3. Commercial products or processes may involve multiple patents with some not funded through federal research;
4. The exercise of march in rights might jeopardise commercialisation of an invention if licensees possess specialist knowledge, trade secrets or other patented technologies necessary to bring a product to market.[51]

In presenting this summary of perspectives on march-in proceedings it is important to emphasise that this has not been used. This has in part been attributed to the complex and lengthy nature of the procedure and concerns about the impacts of march in within technology markets.[52] The three cases where NIH was petitioned to march in are summarised below.

In a petition by CellPro against John Hopkins University and Baxter Health Care filed in 1997, CellPro petitioned the National Institutes of Health to march in on patents relating to stem cells and monoclonal antibodies arising from federally funded research that were alleged to be broad in scope. The patents had given rise to infringement proceedings against CellPro arising from a failure on the part of CellPro to pay an upfront fee of $750,000 and running royalties of 16% to Baxter (the University's licensee).[53] When agreement was not reached, Baxter reportedly demanded exclusive foreign distribution rights to CellPro products while CellPro sought to overturn the main disputed patent in what became five years of litigation. In the absence of resolution CellPro petitioned the NIH to march in on the grounds that under Bayh-Dole:

a) Baxter had not achieved practical application within a reasonable time;
b) Action was necessary to alleviate health or safety needs not reasonably satisfied by the contractor or licensees (Baxter) that was in fact provided by the Cell Pro FDA approved Ceprate SC system.

In denying the petition the Office of the Director of the NIH held that: a) Hopkins and Baxter had taken effective steps to achieve practical application, as demonstrated through licensing and the sale of a particular product, and; b) that Hopkins and Baxter had refrained from fully exercising their patent rights in the absence of approval of the alternative product for which they were seeking FDA approval and the continued sale of CellPro's product.[54] In considering the merits of CellPro's argument the Office of the Director observes that:

> "We are wary... of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies. The patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the development and dissemination of new and useful technologies. It has proven to be an effective means for the development of health care technologies. In exercising its authorities under the Bayh-Dole Act, NIH is mindful of the broader public

health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research."[55]

The second case in 2004 arose from letters from members of Congress requesting march-in on patents held by Abbott Laboratories following a reported 400% increase in the price of the Norvir treatment for HIV/AIDs. In this case the Office of the Director similarly held that the practical application and health and safety requirements of the Bayh-Dole Act had been met, while effectively deferring a decision to march in on the basis of price to Congress as a legislative matter. In particular the Director did not view march in as "an appropriate means of controlling prices" and expressed concern about the impacts on wider market dynamics linked to licensing rights under the Bayh-Dole Act. [56]

In the third case, again from 2004, the NIH received requests from the public to march-in on patents owned by Pfizer for Xaltan as a treatment for glaucoma. The petition was based on the high price of Xaltan in the United States compared with other countries. The Office of the Director again found that the practical application and health and safety requirements of the Act had been satisfied and reiterated its opinion in the Abbott case that march-in is not an appropriate means of controlling prices and that pricing was a matter best addressed by Congress.[57]

An additional and separate feature of Bayh-Dole is the requirement to disclose subject inventions to the funding agency. In one case, decided by the Court of Appeals for the Federal Circuit in 2004, title to a gas mask held by Campbell Plastics Engineering (US5895537A) was transferred back to the US Army on the grounds that the correct form for disclosure had not be used and that submissions over the course of the contract had not been sufficient to meet the disclosure requirement. Specifically, in reaching this decision the Court specified that: "Because we conclude that Campbell Plastics failed to comply with the invention disclosure provisions of the contract, we affirm." In this case the patent record did include a statement that: "The U.S. Government has a paid-up license in this invention and the right in limited circumstances to require the patent owner to license others on reasonable terms as provided for by the terms of Contract No. DAAA15-92-C-0082 awarded by The Army." However, in the view of the court the breach of the contract through failure to disclose to the federal agency in the required manner was sufficient to merit transfer of title.[58]

As this discussion makes clear, the United States experienced significant challenges in securing compliance with the disclosure requirement that were mainly overcome using information technology. The debates that have surrounded march in rights and transfer of title are important because they expose issues that are likely to arise if similar disclosure measures are adopted for access and benefit-sharing. This would suggest a need for forward looking scenario planning to create a framework in which particular compliance options may be exercised.

Government Licensing and Indicators:

The disclosure requirements of the Bayh-Dole Act and related legislation ultimately feed into the development of national indicators such as those prepared by the National Science Foundation (NSF). In the context of access and benefit-sharing and disclosure indicators are important in assessing the success of disclosure measures and linking access and benefit-sharing with wider standard indicators.

In the case of the United States national level indicators in this area rely on combinations of reports from federal agencies and organisations such as the Association of University Technology Managers (AUTM). Table 2.1 shows levels of patenting and licensing at United States Universities between 2001-2007 based on data from the AUTM reproduced in the 2010 Science and Engineering Indicators[59]

Table 2.1 Academic patenting and licensing activities: 2001–2007

Activity indicator	2001 (139)	2002 (156)	2003 (165)	2004 (164)	2005 (158)	2006 (161)	2007 (161)
	Millions of dollars						
Net royalties (a)	753.9	868.9	866.8	924.8	1,588.1	1,322.2	1,898.8
Gross royalties (a)	868.3	997.8	1,033.6	1,088.4	1,775.0	1,511.6	2,098.8
Royalties paid to others	41.0	38.8	65.5	54.4	67.8	67.9	63.7
Unreimbursed legal fees expended	73.4	90.1	101.3	109.2	119.1	121.5	136.3
	Number						
Invention disclosures received	11,259	12,638	13,718	15,002	15,371	16,855	17,677
New U.S. patent applications filed	5,784	6,509	7,203	9,462	9,306	10,748	10,899
U.S. patents granted	3,179	3,109	3,450	3,268	2,944	2,895	3,291
Startup companies formed	402	364	348	425	418	500	510
Revenue-generating licenses/options	7,715	8,490	8,976	9,543	10,251	10,733	12,467
New licenses/options executed (b)	3,300	3,660	3,855	4,087	4,201	4,192	4,419
Equity licenses/options	328	373	316	318	278	357	377

NA = not available

[a] One-year spikes in royalty data reflect extraordinary one-time payments.

[b] Data prior to 2004 may not be comparable with data for 2004 and beyond due to change in survey wording.

NOTES: Number of institutions reporting given in parentheses. Data from non-university hospitals and medical institutes not included. Responding institutions may report for any 12-month period ending in the identified year.

SOURCE: Association of University Technology Managers, AUTM Licensing Survey (various years).

Science and Engineering Indicators 2010

This type of reporting ultimately links up, albeit in ways that are not immediately transparent, with wider reporting by federal agencies. In the United States federal funding for research and development in higher education amounted to approximately 60% of $51.9 billion of research and development funding support for universities and colleges in Fiscal Year 2008.[60] Table 2.2 shows the top six agencies responsible for supporting research between 2001 and 2007.

Table 2.2: Federal contributions to Academic R&D by agency for selected years

Appendix table 5-3

	Federal obligations for academic R&D, by agency: 1970–2009							
Year	All agencies	DOD	DOE	NASA	NIH	NSF	USDA	All other agencies
	Current $millions							
2001	19,588	2,285	743	942	11,528	2,498	652	939
2002	21,290	2,219	762	1,075	13,062	2,696	592	885
2003	22,693	1,934	790	1,096	14,350	2,978	641	904
2004	24,170	2,036	854	1,171	15,184	3,122	653	1,150
2005	24,842	2,192	831	1,098	15,657	3,072	710	1,282
2006	24,336	2,096	858	975	15,489	3,112	727	1,079
2007	25,252	2,319	765	553	16,569	3,266	723	1,057
2008 (preliminary)	25,709	2,450	849	544	16,806	3,319	800	941
2009 (preliminary)	25,724	2,104	944	540	16,797	3,901	539	899

Source: National Science Board, Science and Engineering Indicators 2010. Appendix table 5-3, Federal obligations for academic R&D, by agency: 1970–2009

Ascertaining the proportion of reporting that relates to the Bayh-Dole Act, rather than related legislation, for these federal agencies has proved somewhat challenging. Table 2.3 presents aggregated data for federal technology transfer. Table 2.4 presents a breakdown of the data for fiscal year 2007 for the main federal agencies.

Table 2.3: Federal technology transfer activity indicators for U.S. agencies by Fiscal Year

Agency	2001	2002	2003	2004	2005	2006	2007
Invention disclosures and patenting							
All 10 agencies							
Inventions disclosed	3,962	4,149	5,106	5,454	4,771	5,193	4,486
Patent applications filed	2,175	2,130	2,318	1,768	1,745	1,912	1,824
Patents issued	1,610	1,511	1,631	1,391	1,012	1,284	1,406

Source: National Science Board, Science and Engineering Indicators 2010. Appendix Table 4-43 Federal Technology transfer activity indicators for U.S. agencies with federal laboratories. Years are Fiscal Years.

Table 2.4: Disaggregated Federal technology transfer activity indicators (selected U.S. agency for Fiscal Year 2007)[61]

Technology transfer activity indicator	Total	DOD	HHS	DOE	NASA	USDA	DOC
Invention disclosures and patenting							
Inventions disclosed	4,486	838	447	1,575	1,268	126	32
Patent applications filed	1,824	597	261	693	105	114	7
Patents issued	1,406	425	379	441	93	37	4
Licensing							
All licenses, total active	10,347	460	1,418	5,842	1,883	339	217
Invention licenses	3,935	460	915	1,354	461	339	217
Other intellectual property licenses	6,405	0	460	4,488	1,422	0	0
Collaborative relationships for R&D							
CRADAs, total active	7,327	2,971	285	697	1	230	2,778
Traditional CRADAs	3,117	2,383	206	697	1	184	154
Other collaborative R&D relationships	9,445	0	0	0	2,666	4,084	2,695

CRADA = Collaborative Research and Development Agreement. See Note for further details.

Finally, in considering indicators relevant to technology transfer, licenses are a source of income, albeit minor relative to budget allocations, for some agencies such as the Department of Health and Human Services as detailed in Table 2.5 below.

Table 2.5: Licensing income for the Department of Health and Human Services by Fiscal Year (thousands of US dollars)[62]

	2004	2005	2006	2007	2008
Health and Human Services (HHS)					
Total Income (all licenses active in FY)	56,479	98,542	83,097	88,799	97,609
Invention Licences	56,170	96,485	82,187	67,108	94,712
Other IP Licenses	309	2,057	909	19,128	2,897
Total Earned Royalty Income	39,456	76,695	63,250	70,743	80,805
All Reporting Agencies					
Total Income (all licenses active in FY)	99,515	144,862	138,689	149,928	170,901
Invention Licences	95,182	139,621	134,280	123,999	161,785
Other IP Licenses	4,334	5,241	4,409	23,367	9,116
Total Earned Royalty Income	53,114	92,823	86,348	93,951	117,644

In this section we have demonstrated that reporting requirements ultimately link up with wider indicators for funding activity and income from intellectual property. These indicators are important in assessing the success of particular measures. However, it is important to emphasise that in practice only a small percentage of patents and licenses generate revenue for universities or federal agencies.[63] In the university sector, the majority of technology transfer offices report negative income with a small number of patents generating revenue for a small number of universities.[64]

In the case of the National Institutes of Health, in fiscal year 2009 the NIH collected US$91.2 million in royalties on 250 licences that reported products on the market.[65] However, 83% of overall royalties were derived from 20 products demonstrating that a small number of licences accounted for a large proportion of royalties.[66] Given that the NIH is the organisation most closely involved with natural products, such as taxol, it appears reasonable to expect that a similar situation is likely to arise if exclusive licensing models were applied in the case of access and benefit-sharing arrangements. That is, a small number of licences would be

responsible for the bulk of revenue that may form only a relatively minor percentage of overall budgets. Experience in the United States suggests a need for realistic and evidence based assessment of the value to be generated through patents and licensing as part of access and benefit-sharing arrangements.

2.3 The International Dimension of Disclosure:

The Bayh-Dole disclosure provisions have not informed debates on disclosure under the Convention on Biological Diversity. This is possibly because Bayh-Dole is a principal driver for the commercialisation of research through patents and exclusive licensing in countries such as the United States and those with similar legislation. In contrast proposals for disclosure of origin under the CBD and WIPO are constructed in terms of *preventing* "biopiracy" or "misappropriation" and ensuring benefit-sharing.

Experience in the United States with the Bayh-Dole Act provides useful insights into three aspects of debates on disclosure of origin:

1. The policy purposes underpinning a requirement for disclosure (i.e. promotion of technology transfer leading to commercial products that are useful to the public and protection of the government interest in the same);
2. The construction of legislative and administrative measures to achieve the same (amendments to patent law and creation of regulations affecting funding agencies and, to a limited extent, the patent office);
3. Subsequent efforts to monitor, track and report on implementation and compliance by a national accounting body to the legislative body in accordance with standards of accountability and good governance.

As we have seen above, the available evidence suggests that federal agencies have primarily depended on the voluntary iEdison reporting system to promote compliance by recipients of federal funding. This suggests to us that much could be achieved through the use of information technology to facilitate reporting and compliance in connection with access and benefit-sharing.

Debates on Bayh-Dole within the United States have focused primarily on reporting and patent activity within the United States. In contrast, debates on disclosure under the Convention on Biological Diversity focus on the question of what happens when biological materials and traditional knowledge move beyond a national jurisdiction into the wider world. The question we address here is what insights does experience with the Bayh-Dole disclosure requirement provide for debates on tracking and monitoring genetic resources and traditional knowledge under an access and benefit-sharing regime?

We have seen above that the Bayh-Dole regulations require recipients of federal funding to include the following model clause within patent applications:

> "*This invention was made with government support* under (identify the contract) awarded by (identify the Federal agency). The *government has certain rights* in the invention." (401.14 a, subpara (f)(4), emphasis added)

The rules for patent applications further specify this statement should appear under a section of the specification entitled "*Statement regarding federally sponsored research or development*". This statement appears at the beginning of the main body of the description

immediately following the front page or "biblio" of an application as can been seen from the following example.

SYNTHETIC GENOMES

By J. Craig Venter, Hamilton O. Smith and Clyde A. Hutchison III

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] The present application claims benefit and priority from U.S. Provisional Patent Application Serial No. 60/742,542 filed on Dec. 6, 2005, entitled, "Synthetic Genomes;" the present application is related to U.S. Provisional Patent Application Serial No. 60/752,965 filed on Dec. 23, 2005, entitled, "Introduction of Genomes into Microorganisms;" U.S. Provisional Patent Application Serial No. 60/741,469 filed on Dec. 2, 2005, entitled, "Error Correction Method;" and U.S. Non-Provisional Patent Application Serial No. 11/502,746 filed on Aug. 11, 2006, entitled "*In Vitro* Recombination Method," all of which are incorporated herein by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[002] This invention was made with U.S. government support (DOE grant number DE-FG02-02ER63453). The government has certain rights in the invention.

Armed with the information on disclosure clauses we asked the following question: is it possible to track disclosure from the United States patent system into the international patent system? The answer is yes. However, answering this question requires consideration of the strengths and limitations of different approaches and involves significant challenges.

We began by using the Thomson Innovation patent database to identify applications and grants in the United States collection containing a disclosure statement between 1990 and May 2010. To explore the data we sampled documents for disclosure statements using Word Smith text mining software and tested data capture using a variety of queries. We generated a basic 32,525 results for "Statement Regarding Federally Sponsored Research or Development". We then tested terms such as "federally sponsored" (89,388 raw results), "government has certain rights" (88,435 raw results) results and "United States government has certain rights" (6,546 raw results).

The range of these results revealed that applicants may use a variety of terms to disclose government interest in patent applications. This makes data retrieval uncertain (see Table 2.6). Our maximum result through the combination of different terms was 138,625 results as a possible 'universe' (see Appendix). However, we then discovered that patent applicants frequently include a heading for the statement on federal funding but insert the terms "not applicable" or "n/a". This demonstrates that inclusion of a heading for the disclosure statement is routine practice. However, the routine nature of this practice also has a dramatic impact on the results. Thus, for more detailed queries such as "Federally Sponsored" exclusion of records containing "not applicable" or "n/a" reduced the results set by over 50% from 119,454 raw results to 51,455 results (see Appendix and Table 2.6).

The Thomson Innovation patent database also includes a field for United States patents entitled "Government Interest" that permits searches of preprocessed patent data. This demonstrates that commercial database providers will respond to market demands for such information and will attempt to make this information available to users (i.e. does a government have an interest in a claimed invention?). We present the results of searches of these fields in Table 2.6 and they were consistently lower than our text mining based results. However, at the time our research was conducted Thomson was unable to provide a detailed explanation of how the Government interest field was constructed other than that the information was provided by the USPTO. As Table 2.6 makes clear, stabilising disclosure related data depended significantly on the search terms and field used.

Table 2.6: Experimental Results for Disclosure in US Patents 1990-2010

Search Terms	Applications & Grants	Government Interest (Thomson)
Large query (see Appendix)	69,002	54,870
"Federally Sponsored" or "government has certain rights" or "this invention was made with government support"	51,455	40,411
(Federally sponsored) AND (Research OR Development)	19,335	11,720

Our purpose was not to solve the technical problem of clarity of disclosure of federally funded research in United States patents but to explore it. We therefore selected the intermediate dataset of 51,455 records as a basis for further work (Table 2.7). Using this data we carried out sub-searches for biodiversity related terms (22,158 results) and then limited the searches to a number of International Patent Classification codes to reduce levels of possible noise (18,869 results, see IPC Restricted).

In a series of separate steps the searches were repeated for the Patent Cooperation Treaty, the European Patent Office and Other patent offices worldwide. For each of these datasets we then counted the number of documents (D), and we also identified the number of patent families to which these documents are linked (F and see below). The results are presented in Table 2.7. We will initially concentrate on the numbers of published documents (D) and ignore the family (F) category.

Table 2.7: US Federal Funding Disclosure Across Jurisdictions 1990-2010 [67]

Searches	US		WO		EP		Other	
Family/Documents	F	D	F	D	F	D	F	D
Federally sponsored	32,503	51,455	14,620	16,150	1,237	1,571	62	66
biodiversity terms (raw)	12,707	22,158	8,973	9,895	595	800	6	6
IPC Restricted	10,549	18,689	7,885	8,657	347	747	4	4
INPADOC Priorities	*10,547*	*33,265*	*7,227*	*16,093*	*4,387*	*13,356*	*(21,969)**	*41,829*

Note: Family = number of INPADOC families. *cumulative sum of first family members in other jurisdictions.

The document (D) counts in Table 2.7 immediately suggest that it is possible to track the disclosure statement across jurisdictions. However, it appears that disclosure rapidly degrades as we move across jurisdictions. There are two main issues to consider here:

1) Only a percentage of applications filed in a home country will also be filed under international or regional instruments. Many patents do not travel;
2) Efforts to track disclosure across jurisdictions runs into the use of multiple languages and lack of access to the whole texts of patent documents. This includes lack of access to documents in other English speaking jurisdictions (i.e. Australia, New Zealand & Canada under Other).[68] The coverage offered by patent databases is a very significant factor in data access.

Table 2.7 demonstrates that disclosure endures into the international system. However, in our view no meaningful conclusion can be drawn about the degradation of disclosure because of the second problem identified above. The lesson to be drawn from this is that an effective disclosure requirement must be able to overcome the twin barriers of multiple languages and varying access to the whole text of patent documents in multiple countries.

The question that arises from these limitations is whether a more effective means is available for tracking disclosure across jurisdictions. The answer to this question is yes. However, this requires a more detailed understanding of patent data, notably the concept of the patent family (see box).

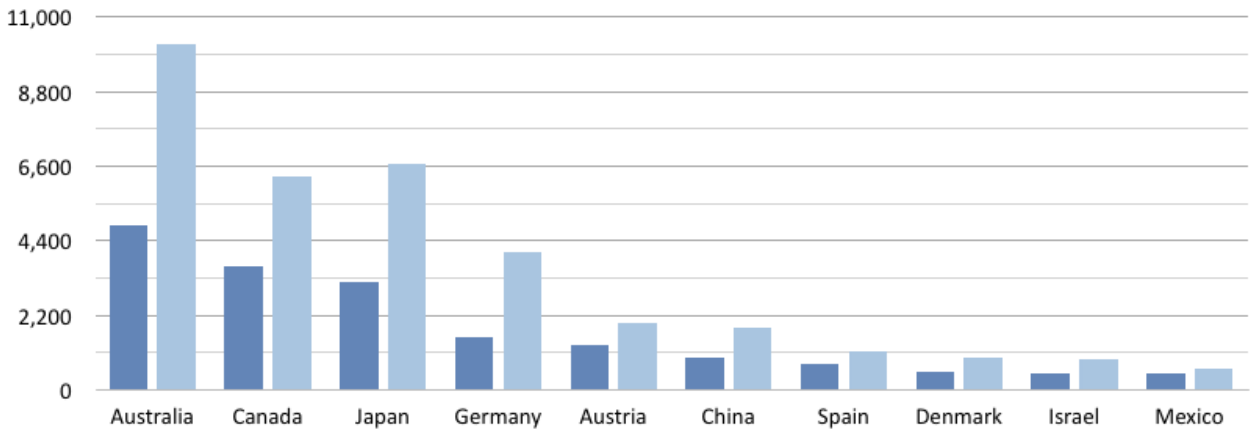
INPADOC Patent Families

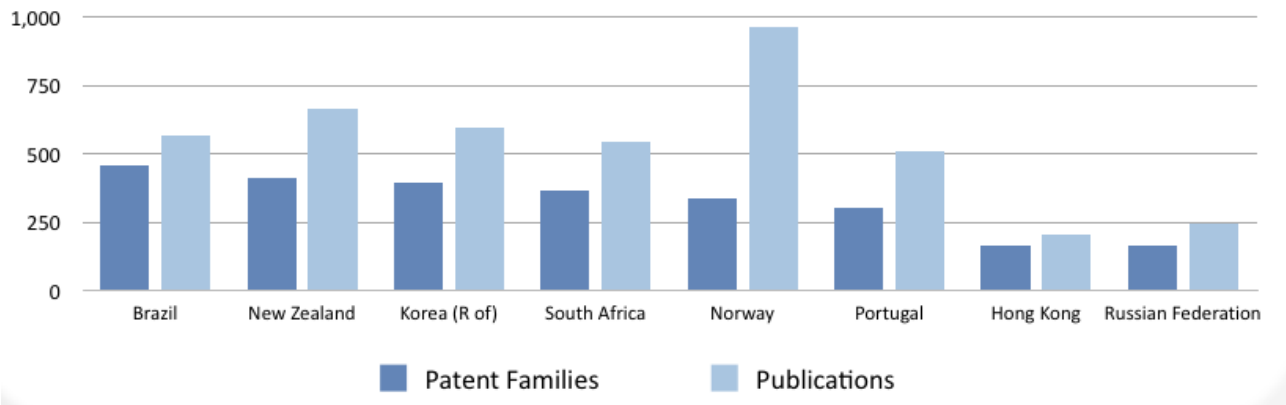
A patent family is created by one or more documents that link to an earlier patent application as its "parent". When an application is filed for the first time anywhere in the world it is awarded a unique "priority" number under the 1883 Paris Convention. The priority number consists of a two letter country or instrument code, a number, and the year and date. Any subsequent application or publication anywhere in the world that contains that priority number is a "child" of this "parent" and forms part of its family. This is the simplest form of a patent family: a group of patent documents that share a common "priority" parent.

There are a number of definitions of patent families. The most widely used patent family is the INPADOC patent family which is accessible through the esp@cenet public database and for statistics in the EPO World Patent Statistical Database (PATSTAT). INPADOC stands for International Patent Documentation Centre and is now part of the European Patent Office. An INPADOC family consists of the simple family provided above, continuation filings (i.e. in the United States) and records that are classified as technically related by patent examiners. The majority (i.e. over 95%) of INPADOC families are of the simple type described in the first paragraph. For an accessible introduction to patent families for statistical purposes see Martinez, C (2010) Insight into Different Types of Patent Families. Organisation for Economic Co-operation and Development, STI Working Paper 2010/2.

Patent families are important because they allow the grouping of documents across jurisdictions through the link to parent priority filings *without the need to rely on language*. Instead, patent families allow us to track links between documents across countries around the world *using only standardised unique identifying codes*. This can be demonstrated by breaking out the data for the otherwise invisible category "Other" from Table 2.7 as provided in Figure 2.1.

Figure 2.1: Tracking US Federal Funding through Patent Families (Other - selected countries)





The importance of moving from using language based analysis to patent family analysis is that we can begin to disaggregate the data for federally funded research across jurisdictions at the assignee and species levels. The top ten patent assignees are shown for a range of jurisdictions in Table 2.8. In reading the table note that the University of California registered 989 original or "priority" filings in our sample. Of these, 782 had family members under the PCT, 535 in Australia (AU), 43 in Mexico (MX) and 39 in Brazil (BR) and so on. Countries are listed using international standard two letter country codes.[69]

Table 2.8: Patent Assignees and Patent Publications by Jurisdiction

Patent Assignee	INPADOC Family Member Country													
	US	WO	AU	EP	CA	JP	DE	AT	CN	ES	DK	IL	MX	BR
UNIV CALIFORNIA	989	782	535	433	362	321	155	141	74	82	56	52	43	39
WISCONSIN ALUMNI RES FOUND	249	164	109	97	79	69	36	31	20	19	8	24	16	11
UNIV WASHINGTON	225	158	125	105	86	90	41	35	25	24	20	22	16	17
SCRIPPS RES INST	198	171	136	135	115	117	57	55	44	38	37	23	33	28
MIT	194	147	73	85	65	71	37	31	14	10	6	6	5	3
UNIV COLUMBIA NEW YORK	192	157	117	76	67	59	20	20	12	10	8	6	8	5
GEN HOSPITAL CORP	190	152	106	110	96	95	48	44	13	21	14	13	9	7
UNIV LELAND STANFORD JUNIOR	186	128	76	75	53	52	24	21	6	11	8	6	7	5
HARVARD COLLEGE	175	134	83	71	64	57	30	27	11	13	10	11	8	4
UNIV MICHIGAN	164	134	81	63	56	47	17	17	15	9	4	12	5	3

Key: US - United States; WO - Patent Cooperation Treaty; AU - Australia; EP - European Patent Convention; CA - Canada; JP - Japan; DE - Germany; AT - Austria; CN - China; ES - Spain; DK - Denmark; IL - Israel; MX - Mexico; BR - Brazil

The important point that emerges here is that an understanding of patent families moves beyond the limitations of language based searching and provides a verifiable means of tracking disclosure across the international patent system.

In practice this also extends to species. We used the Species 2000/ITIS Catalogue of Life list of 1,160,711 million species names to map references to binomial species names within the title abstract and claims within our sample.[70] Table 2.9 maps the species referenced in the title, abstract or claims onto the respective family member countries.

Table 2.9: Species References and Patent Families by Jurisdiction

	INPADOC Family Member Country													
Species	**US**	**WO**	**AU**	**EP**	**CA**	**JP**	**DE**	**AT**	**CN**	**ES**	**DK**	**IL**	**MX**	**BR**
Escherichia coli	88	61	47	43	38	26	15	15	12	7	8	7	8	8
Mycobacterium tuberculosis	43	37	27	21	18	14	8	8	5	2	3	3	2	3
hepatitis C virus	33	29	23	21	18	14	5	5	5	2	2	2	2	1
Pseudomonas aeruginosa	33	26	16	17	14	11	4	4	6	2	3	3	2	3
Saccharomyces cerevisiae	32	21	16	14	14	9	1	1	1			1	3	
Staphylococcus aureus	32	27	18	17	14	10	4	4	6	2	3	3	1	2
vaccinia virus	28	23	14	18	12	10	4	4	8	4	4	3	1	3
measles virus	24	20	13	15	13	9	7	7	2	2	2	3	3	2
Bacillus anthracis	24	20	14	15	9	10	3	2	4	1			1	
Candida albicans	23	18	16	16	14	10	5	5	1	2	2	3	1	
Haemophilus influenzae	23	20	12	11	7	7	4	4	3	3	3	2	1	1
hepatitis B virus	23	20	14	16	14	11	5	4	4	2	1	3	3	1
Salmonella typhimurium	21	17	12	10	8	8	3	3	5	2	2	3	2	2
Listeria mono-cytogenes	21	19	10	13	11	5	1	1	5					
Vibrio cholerae	19	18	13	13	9	9	3	3	6	2	2	2	3	3
Streptococcus pneumoniae	18	13	12	7	7	6	3	3	2	2	2	2	2	2
Helicobacter pylori	17	14	9	5	4	5	2	2	2	1	1	1	1	1

Key: US - United States; WO - Patent Cooperation Treaty; AU - Australia; EP - European Patent Convention; CA - Canada; JP - Japan; DE - Germany; AT - Austria; CN - China; ES - Spain; DK - Denmark; IL - Israel; MX - Mexico; BR - Brazil

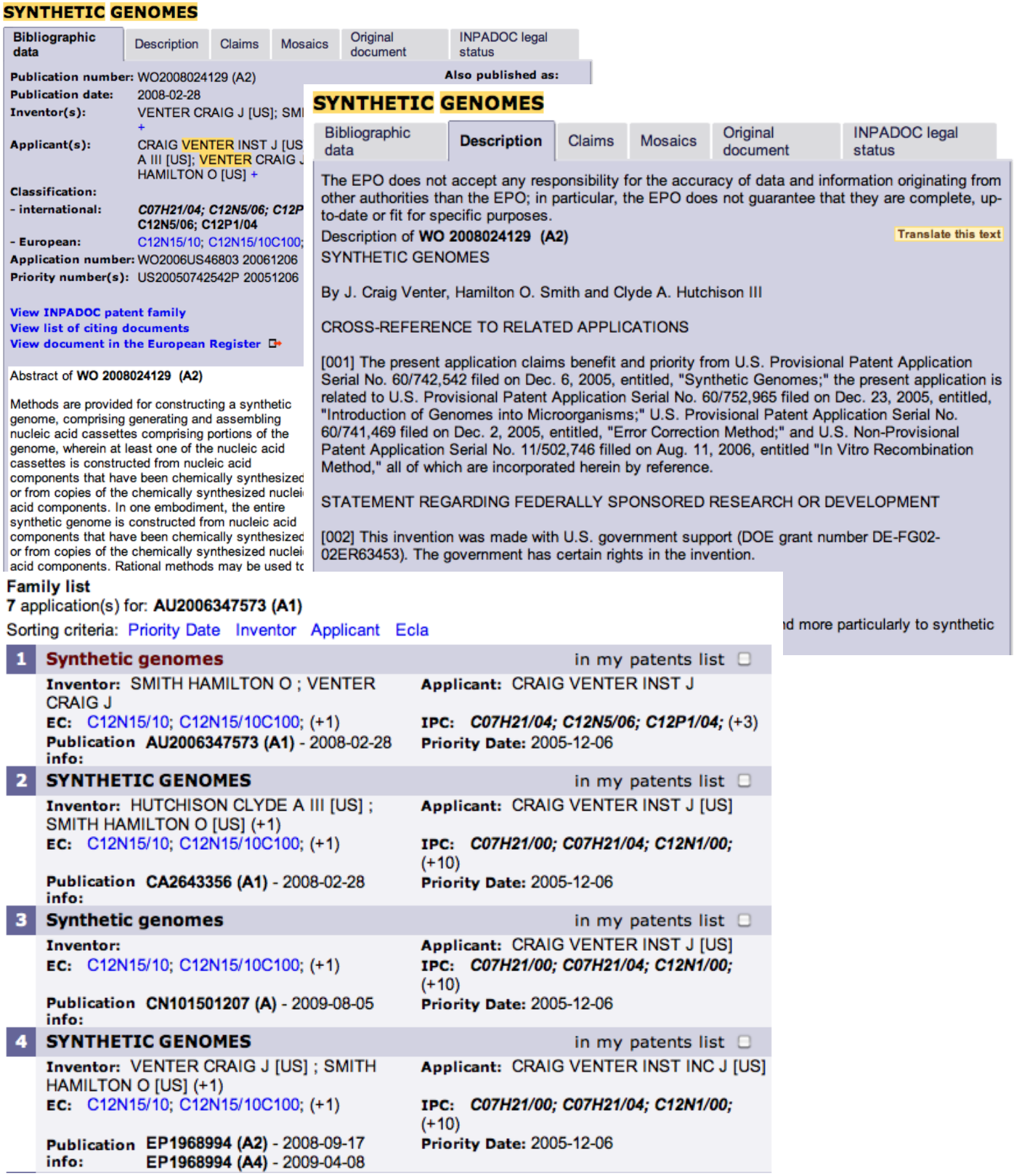
The importance of this approach is that an understanding of the detailed workings of the patent system allows us to transcend the boundaries of language to track disclosure across jurisdictions. That is, starting only with patent data collected from one country (the United

States) it was possible to identify all associated family records around the world through an understanding of INPADOC patent families with no other information being required to identify the records.

For debates on access and benefit sharing this finding has two important practical implications. First, the inclusion of a disclosure requirement in the description section of patent applications makes it possible to identify patent family members in jurisdictions elsewhere in the world using publicly available patent databases such as the European Patent Office esp@cenet database. A topical example from research to create synthetic genomes at the J. Craig Venter Institute filed directly with the Patent Cooperation Treaty will illustrate the point (Figure 2.2) .

This example illustrates that it is possible to track through from disclosure of federal funding (in this case from the Department of Energy) through to family members in Australia (AU), Canada (CA), China (CN), and under the European Patent Convention (EP). In the case of Australia the full text of the Australian version of the application is not available and the US version with the disclosure statement is automatically offered instead. In the case of Canada the Canadian application with the disclosure statement is provided. In China, the translated version of the application is provided, including an identifiable contract number from the Department of Energy (DOE). As this example makes clear, a cost effective means for tracking disclosure already exists in its basic form through the European Patent Office esp@cenet worldwide database.

Figure 2.2: Tracking Federal Funding Across Jurisdictions (esp@cenet)



On a larger scale, the tracking of disclosure should also prove possible for the generation of statistical indicators through the use of the EPO World Patent Statistical Database (PATSTAT) which provides the international baseline for patent statistics (see section 3 for examples). However, as we have seen in the preceding discussion the use of multiple languages can represent a significant barrier to tracking disclosure. For this reason we would recommend

the use of a coding scheme linked to contract numbers that could be displayed in the front page of patent database records consisting of a country code a unique identifier and ABS code (i.e. ABS) to clearly distinguish the required disclosure for retrieval. This type of reference could be extracted from the patent description and inserted into a field such as the citation listing as in the example above. The practical consequence of this would be that it would be easier for countries, civil society organisations and indigenous peoples organisations to track disclosure across multiple jurisdictions and languages. This task would ideally be coordinated by WIPO in collaboration with the European Patent Office as the main repository of global patent data.

Reassignments:

We have seen above that under the Bayh-Dole Act, federal agencies reserve the right to secure and maintain patent rights arising from federally funded research in the United States or elsewhere. This includes federal agencies pursuing patent rights in circumstances where contractors choose not to pursue or maintain patents.

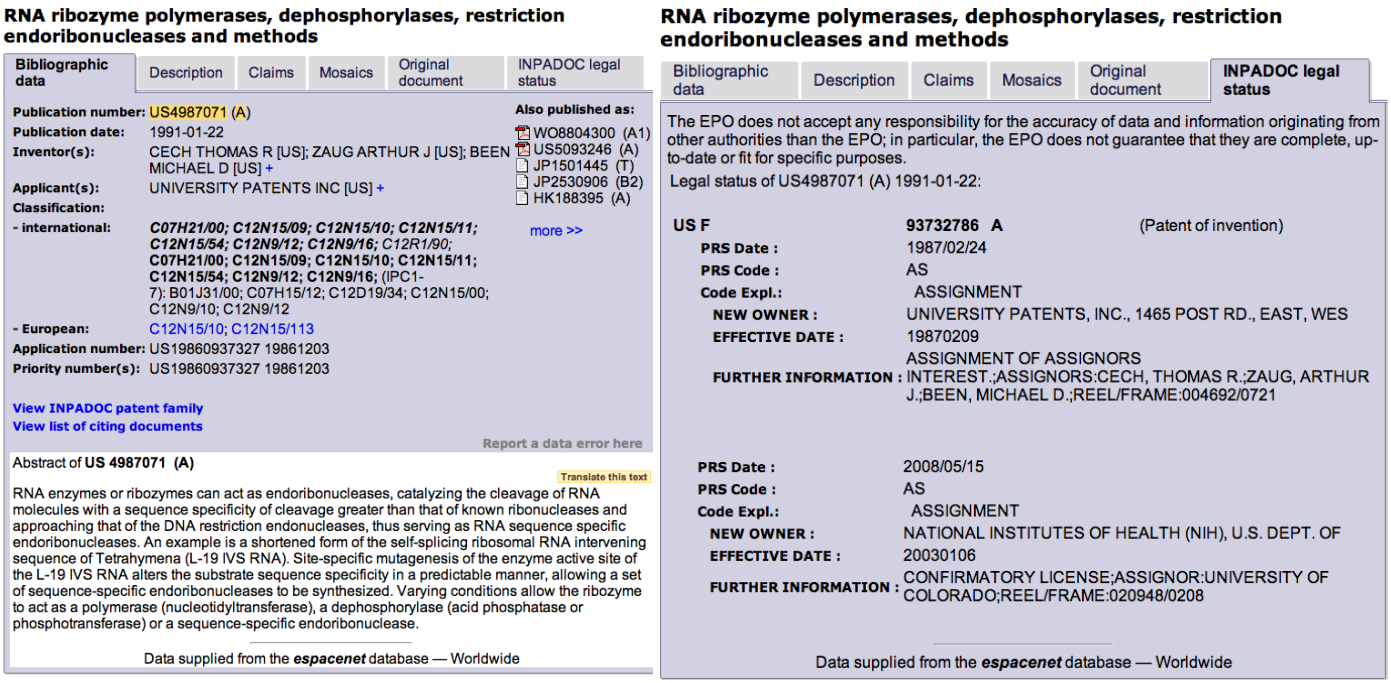
We are not aware of any detailed empirical studies on the extent to which these options are exercised by federal agencies. However, an insight into reassignments is provided for illustration using data from the reassignment field for US records from our sample.

Table 2.10: Reassignments to US Federal Agencies

Reassignments	Families	Publications
Health (HHS)	3418	3795
Energy (DOE)	664	701
Defence (DOD)	335	723
Commerce (DOC)	46	73
Agriculture (USDA)	42	95
NASA	27	54

Reassignments of patent rights (which may include joint ownership) takes form in patent legal status data in entries such as "NATIONAL INSTITUTES OF HEALTH (NIH) U.S. DEPT. OF HEALTH AND HUMAN SERVICES (DHHS) U.S. GOVERNMENT,BETHESDA,MD,US NATIONAL INSTITUTES OF HEALTH (NIH) U.S. DEPT. OF HEALTH AND HUMAN SERVICES (DHHS) U.S. GOVERNMENT" (2,809 families and 2,983 publications in our sample). The data is 'messy' in so far that it can be difficult to access and may take a variety of forms. However, while coverage may vary in practice, information on reassignments may also be available in public databases such as esp@cenet. The following example for RNA ribozyme nucleases originally held by University Patents Inc. in 1987 and subsequently transferred to the National Institutes of Health in 2003 (see effective date) will illustrate the point.

Figure 2.3: Reassignment in Legal Status Data



RNA ribozyme polymerases, dephosphorylases, restriction endoribonucleases and methods

Bibliographic data | Description | Claims | Mosaics | Original document | INPADOC legal status

Publication number: US4987071 (A)
Publication date: 1991-01-22
Inventor(s): CECH THOMAS R [US]; ZAUG ARTHUR J [US]; BEEN MICHAEL D [US] +
Applicant(s): UNIVERSITY PATENTS INC [US] +
Classification:
- international: ***C07H21/00; C12N15/09; C12N15/10; C12N15/11; C12N15/54; C12N9/12; C12N9/16;*** *C12R1/90;* **C07H21/00; C12N15/09; C12N15/10; C12N15/11; C12N15/54; C12N9/12; C12N9/16;** (IPC1-7): B01J31/00; C07H15/12; C12D19/34; C12N15/00; C12N9/10; C12N9/12
- European: C12N15/10; C12N15/113
Application number: US19860937327 19861203
Priority number(s): US19860937327 19861203

Also published as:
WO8804300 (A1)
US5093246 (A)
JP1501445 (T)
JP2530906 (B2)
HK188395 (A)
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Report a data error here

Abstract of **US 4987071 (A)**
Translate this text

RNA enzymes or ribozymes can act as endoribonucleases, catalyzing the cleavage of RNA molecules with a sequence specificity of cleavage greater than that of known ribonucleases and approaching that of the DNA restriction endonucleases, thus serving as RNA sequence specific endoribonucleases. An example is a shortened form of the self-splicing ribosomal RNA intervening sequence of Tetrahymena (L-19 IVS RNA). Site-specific mutagenesis of the enzyme active site of the L-19 IVS RNA alters the substrate sequence specificity in a predictable manner, allowing a set of sequence-specific endoribonucleases to be synthesized. Varying conditions allow the ribozyme to act as a polymerase (nucleotidyltransferase), a dephosphorylase (acid phosphatase or phosphotransferase) or a sequence-specific endoribonuclease.

Data supplied from the ***espacenet*** database — Worldwide

RNA ribozyme polymerases, dephosphorylases, restriction endoribonucleases and methods

Bibliographic data | Description | Claims | Mosaics | Original document | **INPADOC legal status**

The EPO does not accept any responsibility for the accuracy of data and information originating from other authorities than the EPO; in particular, the EPO does not guarantee that they are complete, up-to-date or fit for specific purposes.
Legal status of US4987071 (A) 1991-01-22:

US F	**93732786 A**	(Patent of invention)
PRS Date :	1987/02/24	
PRS Code :	AS	
Code Expl.:	ASSIGNMENT	
NEW OWNER :	UNIVERSITY PATENTS, INC., 1465 POST RD., EAST, WES	
EFFECTIVE DATE :	19870209	
FURTHER INFORMATION :	ASSIGNMENT OF ASSIGNORS INTEREST.;ASSIGNORS:CECH, THOMAS R.;ZAUG, ARTHUR J.;BEEN, MICHAEL D.;REEL/FRAME:004692/0721	
PRS Date :	2008/05/15	
PRS Code :	AS	
Code Expl.:	ASSIGNMENT	
NEW OWNER :	NATIONAL INSTITUTES OF HEALTH (NIH), U.S. DEPT. OF	
EFFECTIVE DATE :	20030106	
FURTHER INFORMATION :	CONFIRMATORY LICENSE;ASSIGNOR:UNIVERSITY OF COLORADO;REEL/FRAME:020948/0208	

Data supplied from the ***espacenet*** database — Worldwide

Reassignment of patent ownership is common in the context of the emergence of intellectual property markets but is poorly understood and lacking in transparency at the level of empirical research. Our sample data suggests that patent rights are regularly reassigned to federal agencies as patent applicants abandon pursuit or maintenance of patents in one or more jurisdictions. Reassignment to US federal agencies in accordance with the Bayh-Dole Act and corresponding contractual provisions does not appear, based on the absence of literature on the topic, to be a major issue.

2.4 Valuing Patents and Patent Licensing:

At the outset of this discussion we emphasised that we are not seeking to promote a Bayh-Dole style model of patent led exclusive licensing. There are two main reasons for this. First, the criticisms levelled at Bayh-Dole for its wider impacts on research and innovation merit more considered attention than can be provided in this paper in terms of models of innovation in the 21st Century. In particular we share a concern that developing countries should not "blindly" import a US model that is now 30 years old but should instead learn the lessons from that experience and design incentive measure that suit their needs in the 21st Century.[71] Increasingly, these incentive measures are characterised by open models of innovation including non-exclusive licensing and open source approaches.[72]

The second major reason for not promoting this model, but instead learning its lessons, relates to expectations about patent value. Debates on access and benefit-sharing have been heavily over-determined by expectations of potential economic value in which patents assume a talisman like status. In practice, it is well established that the value distribution of patents is highly skewed.[73] That is, *only a small percentage of patents are economically valuable or of value to society in terms of an inventive contribution.*

An insight into the value of patents can be gained through citation analysis. This consists of looking at the number of patents that have been cited by other patents and is similar to the

use of citation analysis for scientific publications. However, in the case of patents, citations are important because a cited patent limits the scope of what is claimed by the citing patent.

Citation analysis is affected by factors such as the age of patents with older patents attracting more citations than younger ones.[74] In the case of the biodiversity sample arising from federally funded research in the United States between 1990-2010, a total of 4,939 (46.7%) of the 10,556 documents reviewed had not received a single citation from another patent, 1,191 (11.2%) had received 1 citation and 705 (6.6%) had received two citations. At the opposite end of the spectrum 49 patents (0.46%) had received more than 100 citations with "methods for identifying nucleic acid ligands" (US5270163A) receiving 343 citations.

Looking beyond this data, and using information from citations in the EPO World Patent Statistical Database (September 2009 edition), analysis of citation data for all patents worldwide between 1990-2008 suggests that 82% of all patents worldwide did not receive a single citation. While this is a preliminary finding that merits fuller methodological discussion, the point we wish to highlight here is that high expectations of value from individual patent applications are unlikely to be realised. This is also an important emerging lesson from the increasing trend towards university patenting where the majority of university technology transfer offices reportedly struggle to break even.[75]

A third consideration relates to whether the pursuit of patent rights arising from federally funded research generates a fair return to governments (and thus taxpayers) relative to the wider costs that may be incurred. This is particularly relevant in areas such as health research where federal agencies (notably the NIH in the United States) are major investors in health research but increasing concern has been expressed about the cost of pharmaceuticals arising from government funded research that has been exclusively protected by patents.

These issues are non-trivial for science, innovation and taxpayers because ownership of patents arising from government funded research may be used to demand high licensing fees that limit research in break through areas. Thus, a patent entitled "primate embryonic stem cells" (US5843780A) awarded to the Wisconsin Alumni Research Foundation (WARF) that discloses funding from NIH caused considerable controversy within the research and commercial communities owing to the high cost and restrictive nature of WARF licensing practices. In 2006 the Foundations for Taxpayer and Consumer Rights, with support from the Public Patent Foundation, sought revocation of three stem cell patents held by WARF. The requests were initially granted in March 2007 and the claims subsequently limited in reexamination with one patent revoked.[76]

The problem that emerges here is that the promotion of a patent based model of exclusive licensing may result in significant negative impacts on science, innovation and society. These considerations have become an increasing focus of attention with respect to biotechnology patents in the context of the proliferation of patenting and exclusive licensing. This has led to the development of a variety of guidelines and recommendations on licensing by the NIH[77], the Australian Law Reform Commission[78], OECD[79], and the United States National Research Council (NSC).[80]

The most recent report on these issues in the United States is the Secretary's Advisory Committee on Genetics, Health, and Society (2010) *Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests.* The main recommendations of this report relevant to the relationship between licensing models and disclosure involving genetic resources can be summarised as follows:

1. *Support the Creation of Exemptions from Infringement Liability* with respect to genetic tests and an exemption on infringement liability for research;
2. *Promote adherence to norms designed to ensure access to such tests*. The committee recommended that mechanisms should be created and implemented to "increase adherence to current guidelines that promote non-exclusive licensing of diagnostic genetic/genomic technologies and the creation of a code of conduct to promote broad access to technologies. Drawing on NIH and OECD guidance that discourages exclusive licensing of genetic/genomic inventions they reiterate that "licenses should not hinder clinical research, professional education and training, use by public health authorities, independent validation of test results or quality verification and/or control." In particular, the committee noted that compliance with licensing guidelines could be made a condition of grant awards or regulations could be introduced to limit exclusive licensing.
3. *Enhance Transparency in Licensing*: This recommendation notes the lack of information that is available on licensing and its transparency and recommends that mechanisms should be created to make information on the type of license and field of use for which rights were granted should be made publicly available. The committee further recommended that the NIH amend its guidelines so that license contracts should include a provision allowing the disclosure of non-financial information - specifically, the type of license, field of use and scope - "to encourage next-generation innovation". Finally, the committee recommended that license information should include information on the scope and "whether any rights to use the patented invention remain available".[81]

As these recommendations make clear, in light of experience with developments in genomics a major reconsideration is taking place of the relationship between federal funding, licensing and patents in the United States. This reconsideration has been gathering force for a number of years as the distinctive characteristics of genomics and related developments in science and technology, such as stem cells and synthetic biology, come into greater focus. The trend is towards open and networked innovation that recognises that exclusivity is not necessarily either the best or only means to generate public goods in the form of new and useful products.

When seen from the perspective of experience in the United States, a disclosure requirement emerges as an important tool that enhances the capacity of governments to identify and monitor the positive or negative impacts of the research it supports and to make the necessary policy adjustments based on evidence based assessment and practical experience. Indeed, our research suggests that the United States could make greater use of available information on the disclosure of federal funding in patent applications in assessing federally funded research outcomes than is presently the case.

Conclusions:

The Bayh-Dole Act provides an example of a fully functioning disclosure requirement that is embedded in patent law. It is useful as a proxy for a disclosure requirement under the international regime on access to genetic resources and benefit-sharing because it provides a range of insights and lessons learned on how disclosure might function and be tracked around the world.

Experience in the United States demonstrates that monitoring and enforcement of Bayh-Dole terms and conditions and corresponding disclosure was limited into the 1990s but became an increasing focus of attention in the late 1990s and early part of this century. This led to the creation of the iEdison database system as a cost effective online reporting system for use by

applicants and federal agencies as the principal monitoring instrument. There are clear lessons here for the establishment of an ABS Clearing House Mechanism and national level monitoring and reporting systems. That is, parties to ABS contracts should be required to report to ABS authorities on applications for intellectual property rights. This will most readily be done using electronic systems.

The disclosure requirement for federal funding is detailed by the United States Patent Office as a line item in the structure of patent applications. This does not appear to have created major issues either for users of the patent system, who routinely include the relevant heading and information, or for the USPTO at the level of work load. We are therefore compelled to conclude that arguments that disclosure requirements inevitably create a heavy burden for applicants and patent offices are not supported by experience in the United States. Disclosure is routine.

Analysis of empirical data on disclosure in patent documents revealed that in practice while applicants appear to engage in disclosure they do not always do so in a uniform way. That is they may use a variety of terms and clauses rather than the standard heading and clauses provided in the regulations. This speaks to the need for clear guidance to applicants on the precise textual form and position of disclosure within patent documents to facilitate monitoring.

Our exploration of the international dimension of disclosure of federal funding in United States patent applications in foreign jurisdictions revealed that text based searching of documents suggests that disclosure appears to degrade across jurisdictions. In practice this may be more apparent than real because of the use of multiple languages and variations in access to the whole text of patent documents. This could be addressed through the use of standardised coding systems (i.e. country codes and identifiers for references to contracts/certificates) to accompany a disclosure statement.[82] This would allow for the ready and accurate retrieval of information on disclosure by countries and others.

INPADOC patent families are a well established feature of the patent system that allow documents to be tracked worldwide. We demonstrated that it is possible to track documents containing disclosure of federal funding from the United States patent collection around the world using knowledge of patent families and to drill down to the applicant and species level in those jurisdictions. We would suggest that a combination of making disclosure statements visible in patent databases (i.e. esp@cenet) should be accompanied by the more specialised use of patent families to facilitate tracking and the development of indicators. This dual approach would have the advantage of making clear to readers that a patent falls within the ABS regime and provide reputational gains for applicants in demonstrating compliance. The use of patent families would allow for accurate monitoring and facilitate the development of national and international statistics. It would also allow for the economic analysis of technology spillovers from biodiversity and traditional knowledge related activity.[83]

We also established that a cost effective form for monitoring disclosure using the patent family approach already exists in the form of the EPO esp@cenet worldwide patent database and the EPO World Patent Statistical Database (PATSTAT). The first allows for tracking of individual known documents or applicants. The second provides the international baseline for large scale global tracking and statistical analysis.

Experience in the United States demonstrates that a disclosure requirement in the form of a statement in the description section of a patent application is not controversial. With respect

to access and benefit-sharing for genetic resources and traditional knowledge we make the following recommendations.

1. Statement on Access and Benefit-Sharing

Countries participating in the international regime on access to genetic resources and benefit-sharing may wish to encourage the use of a heading in the *description* section of patent applications providing information such as:

a) The contract number and link to any corresponding electronic license/certificate setting out the basic terms and conditions under which genetic resources and traditional knowledge were provided;
b) Competent authorities (as stipulated in the underlying contract);
c) Retention of rights by provider countries and participating indigenous peoples and local community designated authorities;
d) Terms of use, including the scope of any license and availability for use;

2. Linking Disclosure Statements to Coding and Patent Families

To overcome the use of multiple languages and varying access to the whole text of patent documents, countries participating in the international regime on access and benefit sharing could:

a) Link the disclosure statement to a standardised code (i.e. ABS) that could feature in the front page of records in patent databases such as the European Patent Office esp@cenet worldwide database to allow ready tracking of disclosure to increase confidence among participants in the international regime. This information could be coded into the citation field of existing databases which already includes specialised codes (i.e. XP for literature references in the EPO collection).

3. Tracking Compliance:

The INPADOC Family field provides a secure means for large scale tracking of compliance using online databases and the EPO World Patent Statistical Database (PATSTAT). This is a well established and reliable system. However, use of this system requires specialist knowledge and tools. Countries could usefully encourage the use and further development of PATSTAT to address ABS needs.

4. Developing Indicators:

One problem confronting debates on access and benefit-sharing is the lack of transparency and visibility of patent activity for genetic resources and traditional knowledge. Building on existing work countries could promote the wider use and development of electronic systems to make patent activity visible and the development of accurate, reliable and verifiable indicators using the EPO World Patent Statistical Database (PATSTAT) and other tools. The development of indicators would improve transparency and certainty and thus contribute to trust under the international regime.

3. Interrogating Disclosure

3.1. Introduction:

Debates on disclosure of origin have been characterised by legal and policy analysis of the potential implications of different disclosure requirements.[84] The most recent work on disclosure is being performed by the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC). At the 16th Session the IGC considered a range of country reports on disclosure measures that forms the basis for the empirical data presented in this section.[85] Previous reports typically point to the newness of disclosure measures in particular countries, their narrowness and the problem of lag times between the filing of applications and publication.[86] Recent work at WIPO reveals that as these measures move into effect countries will be able to generate a range of practical insights from actual experience.

Our research sought to contribute to practical analysis by focusing on empirical evidence for disclosure within the existing patent system as a basis for the development of recommendations on how disclosure might work in practice. We focused on five research questions:

1. To what extent do references to country names already appear in the patent system?
2. What are the general characteristics of references to countries within patent documents?
3. To what extent do patent applicants make reference to countries and regions in patent documents for plant based medicines as a well defined area of the patent system involving biodiversity and traditional knowledge?
4. What insights can be gained from analysis of references to country names within patent documents from countries requiring disclosure of origin?
5. How might recognition of the rights of indigenous peoples be secured in the development of disclosure measures?

In this section we focus on the first four of these questions. To address these questions we used the Thomson Innovation patent database of 69 million records including the whole texts of patents for the main jurisdictions, Vantage Point analytics software from Search Technology Inc. and Word Smith corpus linguistics software from Oxford University Press for text mining the data.

Our research revealed four basic challenges in empirical analysis and monitoring of disclosure:

a. Limitations in the availability of the whole text of patent documents outside the main patent offices;
b. A need to overcome the use of multiple languages;
c. A need to access the whole text of patent filings following the adoption of a disclosure requirement;
d. A need for a ready means to analyse large numbers of documents.

The technical and methodological challenges involved in the discussion presented in this section form an important outcome of this research. Specifically, we conclude that the principal challenge involved is not so much disclosure *per se*, but addressing the clarity and form of disclosure. For this reason we favour the term *enhanced disclosure*.

In this section we begin by considering the general evidence for disclosure of country names in patent documents. We then examine references to country names in an area of the patent library system referring to plant based medicines. We then explore the available data for countries that have introduced disclosure requirements.

3.2 Country Names in Patent Data: General Considerations

An important question in considering debates on disclosure of origin is the extent to which applicants already reference the country of origin or source of material and knowledge disclosed in patent applications. This question links to the well established requirement for adequate disclosure as part of the substantive "teaching" requirement of patentability. That is, a person with ordinary skill in the art should be able to practice the invention to meet the purposes of the patent system. As Spain has observed in early contributions on disclosure, applicants can be expected to disclose the origin of a species where the species is rare and unusual in order to meet the substantive requirements of patentability. [87]

On a wider level it is worth asking the question: are references to countries "new" within the patent system? To test this question we entered a list of 204 country names from Parties to the CBD, including obvious variants, into the commercial Thomson Innovation database and searched for all references to country names between 1990 and May 2010. The results are presented in Table 3.1.

Table 3.1: Country References in Patent Documents

	All Fields	Biodiversity sample (raw)	IPC Limited
All Fields	1,450,459	476,284	401,369
Description	1,426,853	471,115	397,113
Title/Abstract/Claims	38,286	4,632	4,335

Source: Thomson Innovation, May 2010

Table 3.1 reveals 1,450,459 raw references to country names all fields of patent documents published between 1990 and 2010. References to country names are therefore a well established feature of the patent system.

We then narrowed the search to country references linked to a set of biodiversity related keywords including "family" or "genus" or "species" or "plant extract" or "natural extract" or "genome" or "synthetic biology" or "synthetic genomics" or "metabolic engineering". The aim here was to capture a spectrum of biodiversity related terms including emerging areas of science and technology such as synthetic biology and metabolic engineering. Table 3.1 (Biodiversity Sample) establishes that biodiversity related terms frequently occur in conjunction with country names.

Because keywords may have multiple and non-obvious uses (i.e. species of compounds) the searches were narrowed using a set of International Patent Classification (IPC) library codes identified in research for the European Environment Agency on ABS indicators as part of the 2010 Biodiversity Target indicators.[88] Across all fields we identified 401,369 records that contained country names and our set of biodiversity related terms. We are therefore

compelled to conclude that country names routinely feature in conjunction with biodiversity and traditional knowledge related terms in patent documents.

An important feature of these results is that the majority of references to country names (397,113 documents) are located in the description (specification) section of patent documents (see box). This is important because in practice, access to the whole text of patent documents in patent databases is typically limited to the main jurisdictions (the United States, European Patent Office, Patent Cooperation Treaty, Japan) presenting a limitation in access to data. It also became clear that the use of multiple languages, including multiple variant spellings of country names, will lead to an underestimate of the total number of references to countries.[89]

Understanding Patent Documents:

Patent documents consist of 4 basic sections

1. **The "front page" or "biblio":** this contains basic information such as title, abstract, patent numbers, names and addresses of inventors and applicants and international patent classification codes. Front pages can be adapted to meet emerging needs through the increasing use of patent databases such as esp@cenet i.e. to link to official public registries or scientific literature references;
2. **The description/specification**: this is the bulk of the application and sets out the background to the invention and prior art in the form of other patents and literature. The description also includes details permitting the practice of the invention, such as the source of particular materials or equipment, and examples of embodiments of the invention. This section is central to what is "taught" by patents and to interpretation of the claims. Most references to countries and traditional knowledge or indigenous peoples are found in this section. Patent applicants in the United States include disclosure of federal funding near the beginning of this section
3. **The claims section:** sets out what is claimed by an applicant as new, novel and involving an inventive step and may be drafted in accordance with formulas (i.e. Markush claims). The claims section may include species references but the natural origin of a compound or derivative may not be readily observable from the claims alone.
4. **Drawings or Sequence Listing:** These may form two independent sections but are grouped here. Drawings may include compound structures or diagrams. Sequence listings consist of listings of DNA and Amino Acid sequences claimed in an application.

In practice the European Patent Office serves as the global repository for patent data in the form of the DOCDB database and related services such as the publicly accessible esp@cenet worldwide database. To overcome these limitations we recommend that WIPO and the European Patent Office could lead greater efforts to promote electronic access to patent documents. We also recommend that the limitations on access to the whole text of patent documents could be overcome by coding disclosure into the front page of patent databases using standard two letter country codes and unique identifiers as with existing identifier schemes used in the patent system.

We now turn to consideration of the range of uses of country names in patent documents.

On the uses of country names:

To gain an insight into the uses of country names we examined a sample of several thousand patents in Word Smith corpus linguistics software. This revealed that references to country names fall into the following categories:

1. References to companies located in particular countries as actual or possible suppliers of materials or equipment as part of the disclosure (i.e. Novo Nordisk,);
2. Country names in the titles of publications cited as prior art;
3. Country names as countries of publication of books and literature in prior art literature references;
4. Records where a country name appears in the assignee field (i.e. a government agency);
5. Countries where particular diseases are prevalent;
6. Country names in the names of a species, extract or strain i.e. *A. senegal* or *A. niger*, Sudan R. strain, or Panama Residual Influenza Virus;
7. Countries where a particular product is manufactured i.e. "Neroli oil is obtained by steam distillation from flowers of Citrus aurantiam L. subsp. amara Engel that is mainly produced in France, Italy, Spain, Morocco and Algeria." (EP956859A1)
8. Countries where species are distributed and/or cultivated;
9. Country references in records from Type Culture Collections (i.e. ATCC xxxx)

As this general data makes clear, countries may be referenced in patent documents for multiple reasons. The problem that emerges here is clarity of disclosure with respect to the origin or source of materials contained in applications. We therefore narrowed our focus to a set of predefined biodiversity related records and analysis of countries requiring disclosure on either a mandatory or voluntary basis.

3.3 Traditional Plant Medicines:

As a basis for further work we selected a sample of 29,768 documents for plant based medicines published in the main jurisdictions between 1990 and 2009. The selection was based on International Patent Classification codes.[90]

The International Patent Classification (IPC) was established under the 1971 Strasbourg Agreement and consists of over 70,000 alphanumeric codes that are used by patent offices worldwide to classify the contents of patent documents. In 2008 there were 58 contracting states to the IPC Union and the IPC is administered by WIPO.

The main purpose of the classification is to facilitate the retrieval of patent based prior art by examiners and users of a system encompassing over 60 million documents. The IPC is also the primary means for the development of patent statistics using tools such as the EPO World Patent Statistical Database (PATSTAT). In particular, the IPC overcomes the problem of the use of multiple languages in the identification and retrieval of prior art by patent examiners. The IPC also facilitates the development of international indicators for areas of science and technology (see below).

In 2006, at the request of developing countries, the IPC introduced a set of classification codes under a new code A61K36 for "Medicinal preparations of undetermined constitution containing material from algae, lichens, fungi or plants, or derivatives thereof i.e. traditional herbal medicines". These classification codes refer to plant species on the family, genus and

species level.[91] Figure 3.1 shows global trends in patent publications under the new classifier A61K36 between 1990 and 2008 using the EPO World Patent Statistical Database (September 2009 edition). Figure 3.1 shows the top countries measured on counts of publications. Figure 3.2 breaks out the data by country of publication.

Figure 3.1: Global Patent Trends for Plant Based Medicines (A61K36) 1990-2008

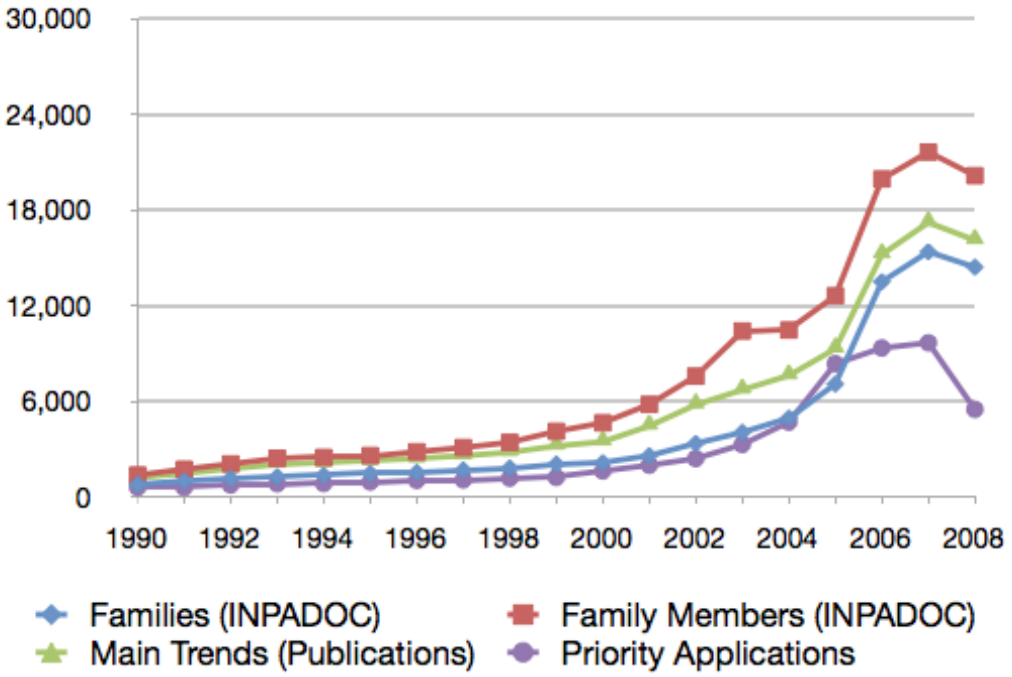
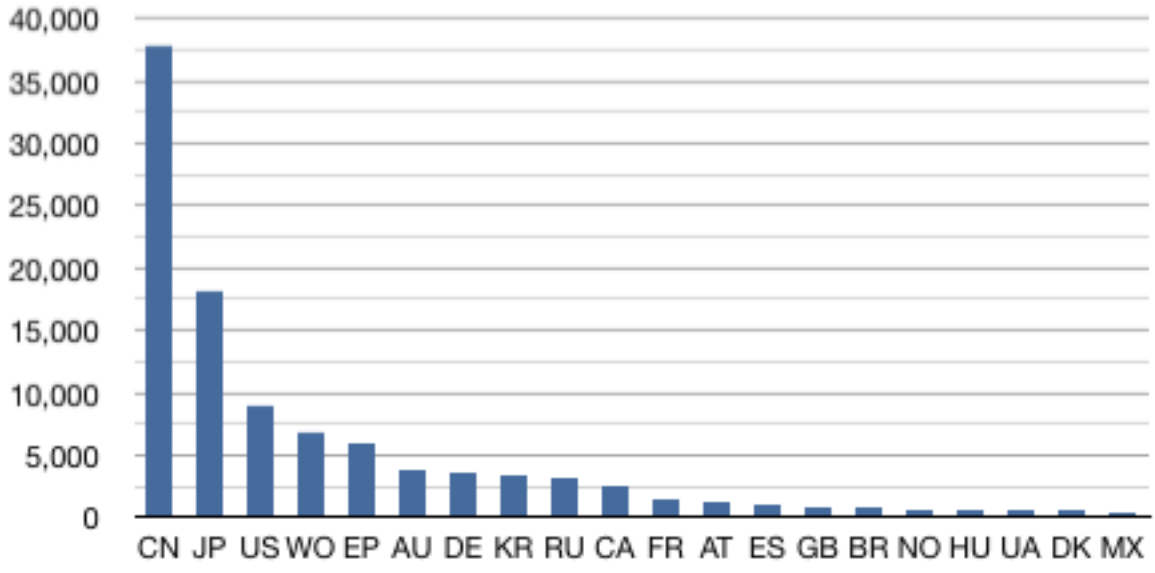


Figure 3.2: Global Patent Trends for Plant Medicines by Publication Country 1990-2008 (Publication Counts A61K36)



Figures 3.1 and 3.2 make clear that patent activity for plant based medicines accelerated rapidly in the 1990s with China (CN) dominating overall publications followed by Japan (JP). In the case of China, filings are typically limited to the national level and reveal a significant problem in identifying country of origin. That is, the use of multiple languages and limitations on access to patent collections. Access to patent documents from China is presently limited to applications in commercial databases such as Thomson Innovation. However, data is generally limited to translations of the title, abstract and claims. Thus, our English search terms in the description section of Chinese patent applications yielded zero results in Thomson Innovation. Lack of accessible documents and the use of multiple languages are a significant issue outside the major patent jurisdictions. As noted above, and discussed further below, these limitations can best be overcome through the use of codes in the front page of documents in patent databases such as the European Patent Office global *esp@cenet* database.

For further work we focused on the main patent jurisdictions consisting of the United States, the European Patent Office, the Patent Cooperation Treaty, France, Germany, the UK and Japan, where the whole text of documents are generally available. We identified 29,078 documents from the main jurisdictions published between 1990 and late 2009 for plant based medicines (A61K36 and the historic code A61K35/78). Of these documents 19,024 contained an available description. As such, 37% of our starting sample lacked an accessible description. Inclusion of documents lacking a description in counts would seriously distort efforts to measure references to country names and needs to be borne in mind in any future efforts to monitor the success or failure of disclosure measures. We therefore limited the analysis to the 19,024 documents containing a description.

The 19,024 documents were searched for all occurrences of country names and region names using Word Smith corpus linguistics software. This revealed 52,788 references to country and region names in 10,893 documents. Based on document counts approximately 56% of our sample contained references to country names. This would suggest that 44% do not. In practice, we believe that the use of English will under estimate the number of references to countries and thereby overestimate an apparent lack of disclosure because we did not capture linguistic differences in country names (i.e. German, French, and other languages).

The top countries and regions referenced in our sample are summarised in Table 3.2.

Table 3.2: Instances of Country Names in Patent Documents for Plant Medicines (A61K36) in the main patent jurisdictions

Country	Instances	Publications	Families	Country	Instances	Publications	Families
China	1046	591	383	Indonesia	58	48	40
India	946	539	327	Israel	58	36	18
Japan	627	461	303	Congo	57	24	5
America	420	314	231	Denmark	53	16	8
Asia	417	349	218	Egypt	50	32	21
Europe	378	313	222	Mongolia	50	48	43
Africa	311	264	173	South Africa	47	46	29
Brazil	278	121	70	Italy	46	34	29
Korea	276	167	103	Madagascar	46	41	17
France	225	169	110	Amazon	42	36	15
Australia	203	140	69	Nepal	42	31	21
Germany	188	147	92	Vietnam	41	37	23
Canada	138	123	83	Nigeria	39	39	33
Peru	116	89	61	Bulgaria	38	14	5
North America	115	112	71	Jamaica	37	28	15

Country	Instances	Publications	Families	Country	Instances	Publications	Families
Thailand	97	63	49	Turkey	35	32	28
South America	89	81	63	Central America	34	30	20
New Zealand*	83	79	68	Netherlands	33	29	13
Pacific	82	74	51	Switzerland	32	25	17
Mexico	79	63	40	Arctic	31	23	7
Malaysia	67	64	40	Sri Lanka	31	25	20
Spain	66	45	29	Paraguay	30	28	15
Polynesia	65	42	20	Iran	29	17	17
Philippines	60	28	14	Argentina	23	23	11
Indonesia	58	48	40	Pakistan	23	23	16
Israel	58	36	18	Guatemala	22	20	13

Data Source: Thomson Innovation. Adjusted to remove false positives such as A. Niger, A. senegal and guinea. * New Zealand data includes New Zealand white rabbits and lipped mussels and is included to indicate impacts on counts. Instances refers to the number of occurrences of a county name. Publications refers to the total number of patent publications. Families groups publications onto their respective first INPADOC family members as priority (first) filings.

We have seen above that country names may be used for a variety of reasons. As such, what this data is telling us is simply the names of countries and regions that are referenced in patent documents for plant based medicines. Thus, one issue that emerged in our data is that country names may form part of species names i.e. *A. niger* or *A. senegal* while partial searches i.e. Guinea will capture references to animals i.e. guinea-pigs for use in experiments as well as actual country references. In other cases, i.e. references to "New Zealand white rabbits", reference may be made to common species sourced from a particular country. For this reason Niger, Senegal and the abbreviation Guinea (for Papua New Guinea, Guinea Bissau, Equatorial Guinea) are not shown in the results.

Taking these limitations into account, what is striking in our sample is the high level of references to country names. The reason for this is that *patent documents frequently refer to more than one country*. Two examples of multi-country references are provided in the box below with <ST> indicating the search term used in mining the texts.

As noted above, the main issue here is not the absence of disclosure, in terms of references to the origin, source or, as we can now see, distribution of species, but the *clarity* of disclosure. That is, country references may appear in documents for a variety of reasons that could give a highly misleading impression if assumed to represent evidence of "biopiracy" or "misappropriation". This raises the question of whether it is possible to move closer to identifying the country of origin or source of a particular species within the data to address the issue of clarity of disclosure? We adopted two approaches to this question:

Examples of Multi Country References in Patent Documents for Plant Medicines (A61K36)

“Medicago sativa or alfalfa, correctly called lucerne, is the principal representative of this family. By plants of the genus Medicago are present on the five continents, especially in France, in the mediterranean basin, in the United States, in Canada and in Australia. The following may be mentioned among the other Medicago species: M. lupulina (Canada), M. truncatula (Australia, South Africa), M. laciniata (arid and semi-arid zones of Australia, Saudi Arabia, Libya), M. littoralis (<ST>Australia), M. minima (Algeria), M. falcata (USSR, Canada), M. media (Alaska) and M. arborea (Greece). The lucernes contain a large variety of substances useful for feeding animals and humans, especially proteins, vitamins, carotenoids and mineral salts (J. G. COORS et al., Crop Science, 1986, vol. 26, no. 5, p. 843-848; E. M. BICKOFF et al. in Alfalfa Science and Technology, ed. C. H. HANSON, published by The American Society of Agronomy, Madison, Wis., USA, 1972, p. 247-282).” (US5723149A; US5770223A)

A second example, this time from two sections of the same document that includes a reference to New Zealand, illustrates the point that references to country names may refer to origin, distribution or to literature on tests on patients in a particular country:

“The use of various plants have been described in ancient Indian Ayurvedic literature. In South India, the plants of genus Phyllanthus and Eclipta alba Hassk are commonly used as a traditional treatment for clinical jaundice including that of viral hepatitis and are commercially available (Thyagarajan, 1986; Thyagarajan & Jayaram, 1992). Phyllanthus species are also used in China, the Philippines, Cuba, Nigeria, Guam, East and West Africa, the Carribean, <ST>Central America and South America. The above two plants have been recently evaluated for their action on Hepatitis B virus. The first screening strategy used was to test the ability of plant extract to coat viral HBsAg, and thereby inhibit the reaction with antibody to HBsAg (anti HBs like activity) (Unander and Blumberg, 1991; Blumberg et al ., 1990). The rationale was that such an inhibition might have effect on pathogenesis of Hepatitis B virus in vivo in man (Mehrotra et al ., 1990, 1991)...

Evaluation of anti-hepadna virus activity on Phyllanthus amarus and Phyllanthus maderaspatensis in duck hepatitis B virus carrier ducks. J. Medical Virol. 1993, 40, 53. * 30. Munshi A, Mehrotra R , Panda SK. Evaluation of Phyllanthus amarus and Phyllanthus maderaspatensis as agents for post exposure prophylaxis in neonatal duck hepatitis B virus infection. J. Medical Virol. 1993, 41, 275. * 31. Milne A, Hopkirk N, Lucas CR et al . Failure of <ST>New Zealand hepatitis B carriers to respond to Phyllanthus. New Zealand Med. Journal 1994 June 243. * 32. Nadkarni KM, Rheum emodi, the Indian Meteria Medica, page 1056-1059. * 33. Nitu J, Wang Y, Qiao M et al . Effects of Phyllanthus amarus on duck Hepatitis B virus replication in vivo . J. Medical Virol. 1990, 32, 212. * 34. Scotto J, Hadchoue L, Hery C et al . Detection of hepatitis B virus DNA in serum by a single spot hybridisation technique.” (EP890360A1; EP890360B1)

3.3.1. Context Words:

In our first test we identified context words such as "from"/"origin"/"source" in conjunction with country names to identify candidates for disclosure of origin or source within the data.[92] To target the test we used a 5 word search horizon to the left or right of the country or region name in the relevant sentence. In the four examples provided <CW> refers to the context term and <ST> to the specific country or regional term.

Our efforts to target disclosure using context words yielded 8,464 references to countries

Context Words Examples

"The invention therefore can provide an excellent agent for treating ulcerative colitis. Best Mode for Carrying Out the Invention Peony root (paeniae radix) as an active ingredient in the treatment agent provided by the present invention is obtained by drying the root of a perennial plant of the peony family (paeonia albiflora var. trichocarpa) <CW>grown in <ST>China, Korea, and Japan or a relative plant. Peony root is used as astringent, emollient, antispasmodic, analgesic, a drug for oversensitive to the cold, and a drug for dermatosis. Further, it is used for abdominal distension, abdominal pain, body pain, diarrhea, purulent tumor, and the like. Peony root is contained in Chinese medicine formulations such as Shao-Yao-Gan-Cao-Tang, Dang-Gui-Shao-Yao-San, Shi-Quan-Da-Bu-Tang (Juzen-taiho-to), Xiao-Qing-Long-Tang (Sho-seiryu-to), Da-Chai-Hu-T..." US6586022B2

"...be considered to constitute preferred modes for its practice. However, those of skill in the art should, in light of the present disclosure, appreciate that many changes can be made in the specific embodiments which are disclosed and still obtain a like or similar result without departing from the scope of the invention. Crude Extract from Vernonia amygdalina Example 1 Aqueous Extraction of Vernonia amygdalina Leaves 1. Fresh Vernonia amygdalina leaves were <CW>collected in Benin City, <ST>Nigeria from pesticide-free plants (it is important to note that the plants investigated in the Kupchan et al. report were collected from east Africa, specifically Ethiopia and thus may represent a Vernonia amygdalina sub-species with properties distinct from employed for use in the instant invention). 2. 18 grams of Vernonia amygdalina leaves were washed three times with distilled water. 3. Next the leaves were soaked overnight (12-18 hours) in 36 mL of distilled water...." US6849604B2

"Cosmetic composition containing an extract of Limnocitrus littoralis The present invention relates to the field of cosmetics. It relates more particularly to novel cosmetic compositions comprising an extract of Limnocitrus littoralis (Miq.) Swingle, hereafter denoted as Limnocitrus littorali.s, and to novel uses of this extract in the field of cosmetics. Limnocitrus litloralis is a plant of the Rutaceae family with the basionym Parainignya littora/is Miq. It <CW>originates from south-east <ST>Asia and, according to our information, is the only species so far indexed in the genus Limnocitrus. Its habitat is essentially located in hot and dry zones. They are shrubs in the form of bushes that are found essentially, but not uniquely, in Vietnam, which is moreover the origin of those used in the description of the present invention. Traditional or religious uses of this plant are related in legends and in Vietnamese literature.... GB2439793A

"The Phlebodium extract contains a plant extract obtained from a plant within the Family Polypodiaceae. The Polypodiaceae family generally includes fems, especially those native to the tropical regions of the world. For example, many of the Polypodiaceae family are <CW>indigenous to Latin <ST>America, especially those in the Honduran rainforests, to South America especially those in the Brazilian rainforests, Mexico, and to the Caribbean islands. The Phlebodium extract is typically obtained from the rhizome or root system, and/or the leaves. The Phlebodium extract is a mixture of one or more of various flavonoids, alkaloids, and/or lipids. Within the Family Polypodiaceae, Phlebodium extracts can be obtained from plants within the Genus Polypodium, the Genus Chrysopteris..." US20060246115A1

with context words in 3,626 documents. This approach radically narrowed the data to 33% of the 10,893 documents containing country or regional names. The reason for this is three fold. First, the use of English terms restricted data capture to only documents in English rather than other languages (notably German and French). Second, the data will also be affected by the choice of search terms. Third, the five word search horizon on either side of the country or regional name significantly narrowed the data. In our view language and the technical challenges of text mining large numbers of documents are the main challenges that need to be addressed using this approach.

3.3.2 Binomial species names:

For our second test we used a list of 1,160,711 binomial species names from the Species 2000 & ITIS Catalogue of Life taxonomic database to identify Latin species names within 1,000 characters of the country or region names within the description sections of the 10,893 documents in our sample.

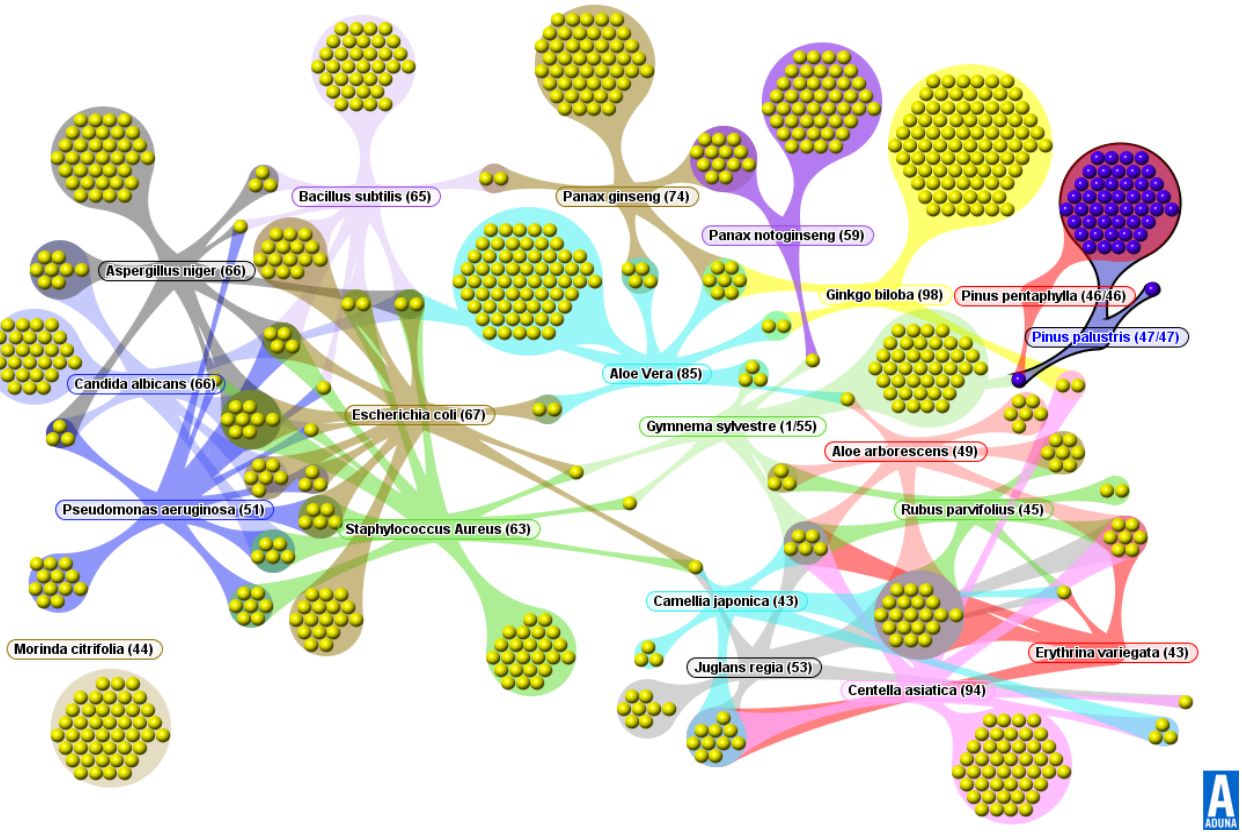
This approach captured 8,754 references to 1,912 species in the description section of 2,893 of the 10,893 records. Again, the dataset has been radically narrowed. This appears to reflect variations in the use of species names by applicants including obvious variants such as abbreviations, single genus or family names and common names. However, one advantage of this approach is that we are able to see the species referred to in the patent documents. Figure 3.3(a) shows a map of the top 20 species referenced within 1,000 characters of country or region names in the description section of the patents.

However, the problem that emerges here, as illustrated in the Box above and visualized for the top 20 species in Figure 3.3(b), is that patent documents may list a range of species and multiple countries within the same sentence or paragraph. This makes it difficult to accurately match a species to a country or region. Furthermore, the referenced species may, as revealed in the case of references to E.coli or A. niger. or B. subtilis, refer to common organisms used in biotechnology based approaches. Other references, notably to viruses, involve treatments targeted to the specific pathogen.

The problem that this presents, as exposed in the network map of linkages between species references and country or region references in Figure 3.3(b) is that it becomes difficult to determine which species originated in which country. This could in part be addressed through the use of narrower search horizons than the 1,000 characters we used for the test. However, as we have seen above, species may also occur in multiple countries and applicants may recognise this in applications. The wider significance of the distribution of species in multiple countries is revealed in Figure 3.4 providing global distribution data for the top 20 species from the Global Biodiversity Information Facility (GBIF).

Figure 3.3: Top 20 Species in Descriptions (a) in conjunction with countries (b)

3.3.a)



3.3.b)

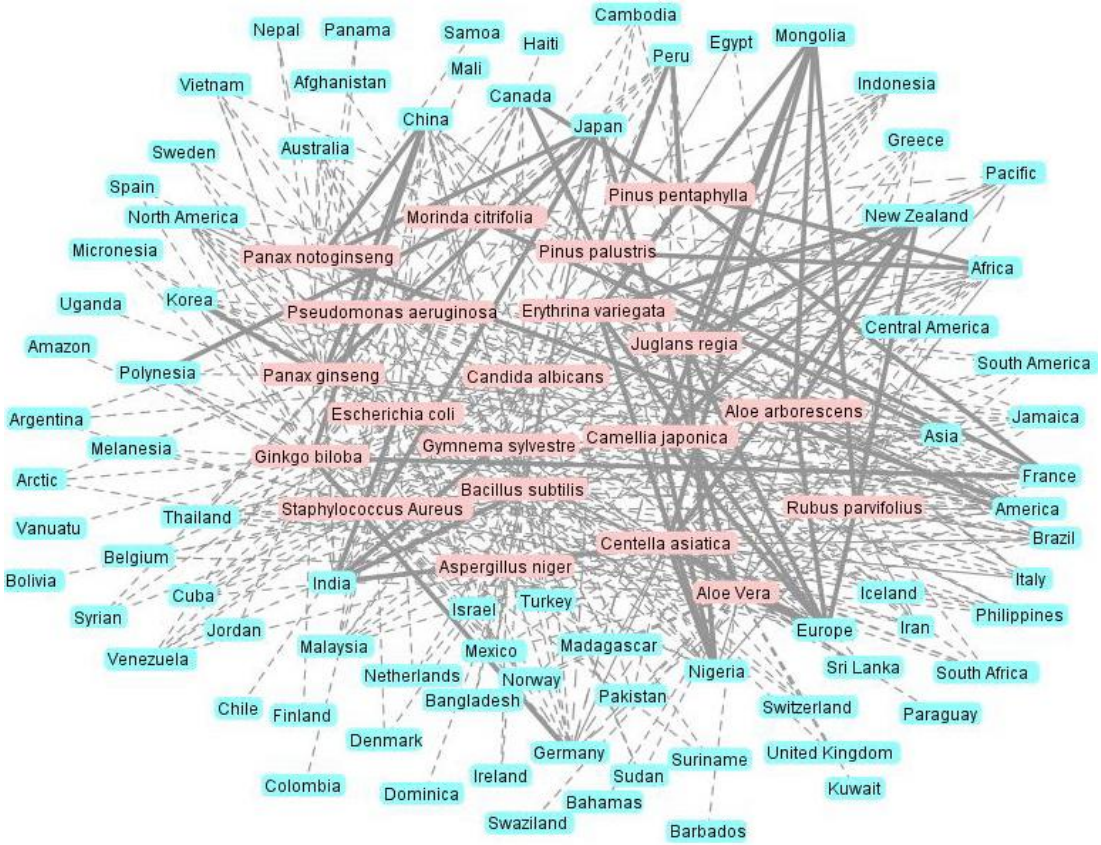


Figure 3.4: Species Distribution Data from the Global Biodiversity Information Facility (GBIF)

The distribution map presented above suggests that species are frequently distributed in more than one country. Species that are unique, in terms of being endemic to a single country, probably represent the exception rather than the rule. More detailed analysis than can be presented here would reveal greater concentrations in particular regions than is provided by the distribution data for the top twenty species. However, this data is sufficient to highlight the biological reality than many species are shared across jurisdictions.

In practice patent applicants are comfortable with multiple listings of the source companies and countries for materials and equipment used in the development of claimed inventions. This suggests to us that greater clarity of disclosure could be achieved where applicants are encouraged to use binomial species names in conjunction with references to the country of origin or source of materials.

In raising this issue we would note that debates on disclosure in access and benefit-sharing appear to be based on a model of "one species/compound = one country" that may potentially be functional in the case of applications for certain pharmaceutical compounds. However, for patent applications ranging from traditional medicines to cosmetics and biotechnology applications involving genetic resources it is more likely that applications will involve multiple species distributed in multiple locations.

A note on patent descriptions and patent claims:

In the preceding discussion we focused on the analysis of references to species in conjunction with country or region names in the description section of patent documents. However, we would note that protection is provided for the uses of a species or its components set out in the claims section of the patent document. In practice our research suggests that a species

name or references to the knowledge, innovations and practices of indigenous peoples or local communities may appear in the texts for a variety of reasons:

1. As a passing reference to function (i.e. illustrating similar properties in other plants or organisms);
2. As part of a literature citation on prior art;
3. As part of an example illustrating possible aspects or embodiments of a claimed invention;
4. As part of the claims.

As a general rule if a particular species is mentioned in the title, abstract or claims (TAC), a strong indication is provided that this is what the patent is 'about', that is that the species referenced will appear in the claims for the invention.

It should therefore be borne in mind that the inclusion of disclosure of the origin or source of a particular species within the description section of a patent application will not necessarily refer to the substantive claims involved.

However, a requirement to name the origin or source of species involved may contribute to improving the wider quality of patent applications. In particular, this could discourage applicants from constructing broad claims to components of species on the genus and family level.

3.4 Countries Requiring Disclosure:

A growing number of countries have adopted disclosure requirements. Table 3.3 sets out available data on the patent portfolios of countries requiring disclosure focusing on applications originally filed in those countries (priority filings).[93] Data on biodiversity is collated from filings in the year immediately following the adoption of the disclosure requirement for each country.

Table 3.3: Patent Portfolios for Countries requiring disclosure[94]

Country	Year	Disclosure Status	Priority Country Portfolio 1990-2010(1)	Biodiversity Sample (2)	Limited by IPC (3)	Description Only (4)
Belgium	2005	mandatory	58,156	245	191	174
Bolivia	2000	mandatory	5	0	0	
Brazil	2001	mandatory	339,385	854	659	575
China	2009	mandatory	2,328,027	-	-	-
Colombia	2000	mandatory	10,572	8	7	3
Costa Rica	1998	certificate	823	5	5	5
Denmark	2000	voluntary	269,462	5,693	5,242	4,853
Ecuador	2000	mandatory	12,407	6	6	5
Egypt	2002	mandatory	7,404	34	27	22
Germany	2005	voluntary	4,666,217	6,107	4,202	3836
India	2005	mandatory	56,867	1,435	1,187	1127
Italy	2006	voluntary	789,666	1,129	809	758
Norway	2004, 2009	mandatory	301,985	405	302	279
Peru	2000, 2002	mandatory	1,812	9	8	8
South Africa	2005	mandatory	150,513	281	213	177
Sweden	2004	voluntary	532,340	2,216	1,796	1,758
Switzerland	2008	mandatory	237,020	62	45	43
Venezuela	2000*	uncertain	109	7	7	7
Total			9,762,770	18496	14706	13630

As a starting point, Table 3.3 reveals that countries that have introduced disclosure requirements have markedly different patent portfolios and levels of involvement in the patent system. Thus, the smallest accessible portfolio is represented by Bolivia while the largest is provided by Germany followed by China. This in turn disguises variations between countries in the use of the patent system on the international level with Chinese applications presently heavily focused on the national level with very limited international activity while Germany is a significant user of the Patent Cooperation Treaty.[95]

We focused on the 13,627 available documents that contained a description for analysis of references to country and region names using the procedure described above.[96] This yielded 44,036 references to countries and regions in 7,782 documents. As such, 57.1% of our biodiversity sample for these countries contained references to country/region names.

Table 3.4 breaks down the data by the country requiring disclose and shows the number of underlying source or "priority" applications, the number of publications that contained country names, the total number of references, the source data and the percentage of the reference publications for each country that included references to disclosure.

Table 3.4 Breakdown of Results by Countries Requiring Disclosure

Dataset	Source Data Publications	Publications with Country Names	Patent Families	No. of Country References	Publications with Country Names as % of Source Data
Belgium	174	114	80	647	65.5
Brazil	575	378	239	1,991	65.7
Costa Rica	5	4	2	65	80.0
Denmark	4,853	3,465	1,425	22,147	71.4
Ecuador	5	2	2	8	40.0
Egypt	22	12	10	46	54.5
Germany	3,836	1,720	1,248	8,867	44.8
India	1,127	575	412	2,560	51.0
Italy	758	273	218	1,143	36.0
Norway	279	135	91	726	48.4
Peru	8	5	3	24	62.5
South Africa	177	93	69	625	52.5
Sweden	1,758	985	600	5,068	56.0
Switzerland	43	17	17	115	39.5
Venezuela	7	4	3	4	57.1
Total	13,627	7,782	4,419	44,036	57.1

Note: Families refers to publications grouped onto their respective INPADOC families as the first filing. Note that results and percentages are affected by the size of source data and language (i.e. Germany).

What is immediately clear from Table 3.4 is that the majority of the documents within the datasets contain references to countries or regions. In particular, countries such as Denmark display surprisingly high scores relative to the size of the record set. The question that arises here is which countries are being referred to in this data? Table 3.5 breaks out the results to show the main frequencies of references to countries.

Table 3.5 Breakout of country references in patents from countries requiring disclosure (Publication Counts)

	DE	DK	SE	JP	NL	CH	FR	IN	BE	CA	NO	BR	CN
Denmark	1449	2056	831	482	602	373	346	38	141	144	197	57	132
Germany	1056	53	44	286	116	161	103	48	87	53	22	27	121
Sweden	327	182	623	69	72	88	63	9	77	104	59	4	12
India	127	15	21	83	11	30	17	381	4	39	5	12	47
Brazil	38	21	7	64	4	9	36	32	3	13	4	264	30
Italy	74	23	24	27	9	12	22	7	20	18	5	2	12
Norway	34	13	17	21	16	23	17	1	12	8	84	1	1
Belgium	42	20	6	15	25	8	20	1	64	8	8	2	2
South Africa	37	2	2	9	10	7	6	5	1	4			7
Switzerland	6	3	3	4	1	5	3		1	1			1
Egypt	2			2	1		1						
Costa Rica	5	4		1		1							1
Venezuela				1									
Peru						1							
Ecuador						1					1		

Key: DE-Germany; DK-Denmark; SE-Sweden; JP-Japan; NL-Netherlands; CH-Switzerland; FR-France; IN-India; BE-Belgium; CA-Canada; NO-Norway; BR-Brazil; CN-China. *Regional references to Europe and America omitted.

Table 3.5 Breakout of country references in patents from countries requiring disclosure (Publication Counts) (Continued)

	FI	Africa	IT	AU	Asia	UK	US	TR	IE	NZ	AT	ES	ZA
Denmark	181	81	80	139	79	130	70	79	99	61	52	50	22
Germany	27	45	28	47	60	37	56	44	18	11	38	20	6
Sweden	82	9	22	17	10	36	39	20	10	18	27	8	5
India	11	43	15	25	63	13	7	8	2	15		7	7
Brazil		48	11	21	30	9	12	3		20	4	20	17
Italy	5	13	112	4	8	9	2	5	2	8	3	7	3
Norway	9		7	3	2	2	6	4	8	2	3	4	
Belgium	7	5	3	3	3	6	3	5	9	5	2	3	
South Africa	1	64	2	6	2	6	1			2		2	59
Switzerland			4	1			2				1		
Egypt		3		1	2				1				
Costa Rica			5									4	
Venezuela	2												
Peru			1										
Ecuador	1					1							

Key: FI-Finland; IT-Italy; AU-Australia; UK-United Kingdom; US-United States; TR-Turkey; IE-Ireland; NZ-New Zealand; AT-Austria; ES-Spain; ZA-South Africa.

The data presented in Table 3.5 illustrates patent documents are dominated by references to the country of filing of an application. For example applications originating in Denmark primarily refer to Denmark and so on. However, a wide variety of other countries may be referenced in the documents. Country data can as needed be broken down by assignees (applicants) as illustrated in Table 3.6 for a selection of five countries.

Table 3.6: Top Patent Assignees (Selected Countries)

Priorities	Publications	Patent Assignees	Denmark	Germany	India	Brazil	South Africa
279	824	NOVOZYMES AS	1	1			
206	965	NOVO NORDISK AS	1				
154	243	ASTRAZENECA AB					
132	234	BAYER CROPSCIENCE AG		1			
113	314	BASF AG	1	1		1	
93	208	HENKEL KGAA		1			
83	218	COUNCIL SCI & IND RES INDIA		1	1		
67	78	BAYER MATERIALSCIENCE AG		1			
59	115	EVONIK DEGUSSA GMBH		1			
57	127	BAYER HEALTHCARE AG	1	1			
52	65	MERCK PATENT GMBH	1	1			
48	80	UNIV AARHUS	1				
47	85	GE HEALTHCARE BIO-SCI AB					
45	63	GRUENENTHAL GMBH		1			
41	90	DEGUSSA AG		1			
41	93	HANSEN AS CHR	1				
38	47	WACKER CHEM AG		1			
32	242	MAXYGEN APS	1				
31	69	STATENS SERUM INST	1				
30	48	BAYER SCHERING PHARMA AG	1	1			
30	45	UNIV KOBENHAVNS	1				
27	63	LUNDBECK AS H	1				
26	86	FORSKARPATENT I SYD AB					
25	54	ALK-ABELLO AS	1				
25	38	BAYER CROPSCIENCE GMBH		1			
25	58	FUNDACAO AMPARO A PESQUISA DO ESTADO				1	
24	39	FIOCRUZ FUNDACAO CRUZ OSWALDO				1	
23	47	UNIV FEDERAL MINAS GERAIS				1	
21	38	SANOFI-AVENTIS DEUT GMBH		1			
11	18	CSIR (South Africa)					1
10	17	UNIV WITWATERSRAND JOHANNESBURG					1
9	12	UNIV CAPE TOWN					1
8	10	SYNGENTA PARTICIPATIONS AG					1
6	6	UNIV STELLENBOSCH					1

Table 3.6 demonstrates that a range of actors from different sectors are captured in the data with the Danish biotechnology companies Novozymes and Novo Nordisk ranking top in the

results, and with previous experience in access and benefit sharing discussions. We now provide a brief selection of examples from the countries referenced in the applications.

Brazil

Brazil, along with China and India, is becoming increasingly active in intellectual property markets involving biodiversity and traditional knowledge. As the two examples reveal this will involve universities as key drivers of bioeconomy related activity. This suggests the impacts that enhanced disclosure measures may have on universities. It also points to the importance of universities as major recipients of government funding in promoting best practice in disclosure.

One example relating to the Amazonian frog Phyllomedusa hypochondrialis (WO2003010191A1) from applicants from Brazil Pesquisa Agropec and the University of Brazil concerning a "New Cationic Peptide of Phylloseptin Family Isolated from Skin Secretion of Phyllomedusa Hypochondrialis" contains explicit reference to the origin of the material:

> "The present invention discloses a novel class of anti-microbial peptide, isolated from skin of Phyllomedusa hypochondrialis, a kind of frog native to Amazonian, Brazil."

This application is part of a family of 12 documents including patent grants in Europe, Australia the United States and Canada. The statement on the origin of the species is preserved in the accessible European and United States patents.

A second example from the Universidade Federal de Minas Gerias filed in November 2006 (WO2008061329A2) refers to compositions for blocking calcium channels with a spider toxin from Phoneutria nigriventer. The examples specify that

> "The identification of the species provided in the Instituto de Ciencias Biologicas, UFMG, Belo Horizonte, MG, Brazil. Phoneutria nigriventer spiders were electrically milked using a method that employs safeguards to prevent contamination of the venom by abdominal regurgitate or hemolymph".

The patent has led to subsequent filings in Europe and Canada in a family consisting of five members.

In considering the data from Brazil it is difficult to ascertain whether applicants are disclosing the origin of resources in accordance with the substantive requirements of patentability or with the disclosure requirement established by provisional measure 2.186-16. It is also difficult to ascertain if the knowledge, innovations and practices of indigenous peoples and local communities were involved in the applications.

Denmark:

Our sample from Denmark is dominated by Novozymes and Novo Nordisk who have past experience and engagement with debates on access and benefit-sharing. A review of Novozymes references to countries within the description sections of patents reveals the dominance of references to the sources of materials and machinery used in the claimed applications. When compared with the earlier data for traditional medicines from plants the Novozymes data and related data from Denmark appears unusually specific with respect to the source of materials. This suggests to us that the companies involved are responding to the requirements of the EU biotechnology directive and, in the case of Novozymes and Novo Nordisk, may be conscious of wider access and benefit-sharing issues. One example from Novozymes is helpful in illustrating the nature of disclosure:

WO2002029024A1
Priority year: 2000/2001
Applicant: Novozymes
Title: Nucleic acids encoding polypeptides having proteolytic activity
Selection from Description: The detergents used were obtained from supermarkets in the USA (Tide Mountain Spring, Deep Clean Formula 1999 P&G 40084959) Prior to use all enzymatic activity in the detergent was inactivated by microwave treatment. Swatches: The swatches used were EMP A 1117, obtained from EMPA Testmaterialen, Movenstrasse 12, CH-9015 St Gall, Switzerland, and C 58, obtained from CFT Center For Testmaterials, Hoekerstraat 12, 3133 KR Vlaardingen, The <ST>Netherlands. Reflectance: Measurement of reflectance (R) on the test materials was done at 460 nm using a Macbeth Color Eye 7000 photometer The measurements were done in accordance with the manufacturer's protocol. Evaluation: The evaluation of the wash performance of a protease is determined by the improvement factor of the protease investigated. The improvement factor, I Fdose/response, is defined as the ratio between the slopes of the wash performance curves for a detergent.

Germany:

Germany has the largest patent portfolio of patent filings of the countries that have adopted enhanced disclosure measures. In the case of Germany this involves the voluntary disclosure of geographic information on origin under the EC Biotechnology Directive. Germany has been a major promoter of progress on access and benefit-sharing under the Convention on Biological Diversity through the Bonn Guidelines and investments in capacity building in Africa and South America. As a major player in intellectual property markets greater attention

WO2007131656A1
Applicant: HENKEL KGAA (HENK-C)
Title: SUBTILISIN FROM BACILLUS PUMILUS AND DETERGENT AND CLEANING AGENTS CONTAINING SAID NOVEL SUBTILISIN

The amino acid sequence derived from it comprises 383 amino acids, followed by a stop codon. It is given in the sequence protocol under SEQ ID NO. 2. Of these, the first 108 amino acids are presumably not included in the mature protein, thus presumably resulting in a length of 275 amino acids for the mature protein. These sequences were compared with the protease sequences obtainable from the generally accessible databases Swiss-Prot (Geneva Bioinformatics (GeneBio) S.A., Geneva, <ST>Switzerland; http://www.genebio.com/sprot.html) and GenBank (National Center for Biotechnology Information NCBI, National Institutes of Health, Bethesda, Md., USA). The enzymes summarized in Table 2 below were identified as the nearest similar enzymes. TABLE 2 Homology of the alkaline protease from Bacillus pumilus with the nearest similar proteins. Enzyme Ident. k. Ident. m. Ident. Ident. m. ID Organism DNA DNA Propre Prot. Q2HXI3 Bacillus pumilus 91 91 98 98 Q6SIX5 Bacill...

"...proteases include, for example, the enzymes available under the brand names Durazym®, Relase®, Everlase®, Nafizym, Natalase®, Kannase® and Ovozymes® from the company Novozymes, those available under the brand names Purafect®, Purafect® OxP and Properase® from the company Genencor, the enzyme available under the brand name Protosol® from the company Advanced Biochemicals Ltd., Thane, India, the enzyme available under the brand name Wuxi® from the company Wuxi Snyder Bioproducts Ltd., <ST>China, the enzymes available under the brand names Proleather® and Protease P® from the company Amano Pharmaceuticals Ltd., Nagoya, Japan and the enzyme available under the brand name Proteinase K-16 from the company Kao Corp., Tokyo, Japan. Examples of amylases that may be used according to the invention include the Î±-amylases from Bacillus licheniformis, from B. amyloliquefaciens or from B. stearothermophilus as well as their further developments....

is merited to experience in Germany than is provided in this report. However, this example suggests that the provision of detailed information on sources of materials is not a major issue for applicants.

India:

Access to patent data from India is largely limited to international level applications through the Patent Cooperation Treaty. The national patent collection is not presently accessible for analytics purposes. On the international level patent are dominated by the Council for Scientific and Industrial Research (India) with the following example providing very specific details of sources of material and highlighting the utility of standard identifiers using country codes (i.e. IN).

WO2007144903A2
Applicant: COUNCIL SCI & IND RES INDIA (COUN-N)
Title: A HYBRID CELL VACCINE AGAINST LEISHMANIASIS [KALA-AZAR]
Selection from Description: Therapeutic vaccination with KMP-11 transfected BMDM/Allogeneic BMDC hybrid cells clears both splenic and hepatic parasite burden The virulent L. donovani strain-AG83 (MHOM/IN/1983/AG83) (Originally isolated from a Kala-azar patient, this strain of Leishmania donovani parasite is routinely maintained in this institute. MHOM is a standard World Health Organization nomenclature : IN stands for country of origin "<ST>India"; 1983 stands for the Year of Discovery; AG83 stands for the strain-specific name. The strain is available with the inventors at MCB, Kolkata, India on demand by any interested person/organization for academic and research purposes) used in this study (31) has a different kinetics of infection than the Sudanese (LV9, LV82) and Ethiopian L. donovani used in other studies (32, 33, 34). After AG83 challenge, an exponential rise in both splenic and hepatic parasite burden is observed...

Norway:

Norway has adopted a pro-active stance towards disclosure. However, Norway has noted that to date experience has been limited (WIPO/GRTFK/IC/16/INF/12). The example provides an illustration of references to type culture collections and the use of the phrase “country of origin” in connection with Type Culture Collections. Once again this example highlights that references to unique identifiers and the country of origin can readily become routine practice.

NO2008711A | NO2008885A | NO2009290A | GB20091913A
Applicant: Pharmaq AS,NO
Title - Polyvalent fish vaccines
Selection from Description: A single isolate was deposited on 21 March 2007 under accession number 07032110 (country of origin: Chile). In a similar manner representative isolates of relevant viral species are available, including infectious pancreatic necrosis virus (IPNV, ATCC VR-1318, country of origin: not provided), Viral Hemorrhagic Septicemia Virus (VHSV, ATCC VR_1389, country of origin: Denmark); Infectious Hematopoletic Necrosis virus (IHNV, ATCC VR-1392, country of origin: USA)); Pancreatic Necrosis Virus; Spring Viremia of Carp (SVC, ATCC VR-1390, country of origin: Denmark); Channel Catfish Virus (CCV) (ATCC VR-665, country of origin: USA); Infectious Salmon Anaemia (ISA) virus (ATCC VR-1554, country of origin: Canada).

South Africa:

We highlight three examples from the 69 original filings and 93 publications from South Africa that include references to countries. All are clear examples of the disclosure of the origin and source of material (in South Africa) with specific details of how they may be obtained and relevant deposits, including in one case an email address.

1. US20090202662A1
Applicant: CSIR,Pretoria,ZA
Title: TREATMENT OF ERECTILE DYSFUNCTION AND LIBIDO ENHANCEMENT
Selection from Description: The Applicant has carried out the present process in particular on plants on the species Monosonia angustifolia identified as such by the South African National Biodiversity Institute (SANBI) in Pretoria, South Africa. Plants of the genus Monosonia are members of the Geraniaceae family, and M. angustifolia is a perennial herb with five petalled pink flowers whose geographic distribution is in open grassland throughout South Africa. A herbarium specimen has been deposited at the SANBI in Pretoria under Genspec. No. 39250002. Extracts obtained from Monosonia angustifolia, in particular solvent extracts using a methanol/dichloromethane mixture as solvent, have been shown to be promising for the treatment of erectile dysfunction and libido enhancement in male subjects.

2. WO2009122362A1
Applicant: UNIVERSITY OF STELLENBOSCH,ZA
Title: ASPERGILLUS CARNEUS STRAIN AND USE THEREOF
Selection from Description: The invention describes the isolation and characterisation of an isolated fungus strain, designated Aspergillus carneus (van Tiegham) Blockwitz (CDS 116150) (also referred to herein as ABO374) and its ability to enhance an animal feed such as wheat straw, ruminant feed, fish feed or poultry feed, to a sufficient degree so that its administration to animals results in improved weight gain of the animals...The fungus culture was isolated from alkaline soil of the Fish River Plains in the Eastern Cape, South Africa (approximately 100 km inland).

3. US20070275448A1
Applicant: CSIR South Africa and Oxyrane UK
Title: Methods For Obtaining Optically Active Epoxides And Vicinal Diols From Meso-Epoxides
Selection from Description: All the yeast strains referred to in this and the following examples are kept and maintained at the University of the Orange Free State (UOFS), Department of Microbial, Biochemical and Food Biotechnology, Faculty of Natural and Agricultural Sciences, P.O. Box 39, Bloemfontein 9300, South Africa (Tel +27 51 401 2396, Fax +27 51 444 3219) and are readily identified by the yeast species and culture collection number as indicated. Representative examples of strains belonging to the different species have been deposited under the Budapest Treaty at National Collection of Yeast Cultures (NCYC), Institute of Food Research Norwich Research Park Colney Norwich NR47UA, U.K. (Tel: +44-(0)1603-255274 Fax: +44-(0)1603-458414 Email: ncyc@bbsrc.ac.uk) and are readily identified by the yeast species and culture collection accession number as indicated. The samples deposited with the NCYC are taken from the same deposit maintained by the South African Council for Scientific and Industrial Research (CSIR) since prior to the filing date of this application. The deposits will be maintained without restriction in the NCYC depository for a period of 30 years, or 5 years after the most recent request, or for the effective life of the patent, whichever is longer, and will be replaced if the deposit becomes non-viable during that period. Samples of the yeast strains not deposited at NCYC will be made available upon request on the same basis and conditions of the Budapest Treaty.

As with the examples from Brazil, the above examples highlight the role of government research organisations (CSIR) and universities in adopting and disseminating enhanced disclosure measures. In the examples above the disclosure of sources provided can be said to promote disclosure as a substantive requirement of patentability (the ability to reproduce an invention) and the requirements for enhanced specifics of sources. The third example highlights that applicants can provide very specific details on the location of relevant deposits including contact details and an email address for the National Collection of Yeast Cultures (NCYC) sponsored by the Biotechnology and Biological Sciences Research Council (BBSRC) in the UK.

Conclusions:

In this section we have examined the nature of existing disclosure of country names within patent applications in conjunction with biodiversity as a subject of empirical enquiry within the patent system. In conclusion for this section we note the following major points:

1. References to country names are routine in patent applications and in patent applications involving biodiversity and traditional knowledge such as plant based medicines;
2. Country names may appear in patent documents for a variety of reasons;
3. Patent documents for biodiversity may refer to more than one country and reflect the distribution of species in more than one country. In addition, patent documents may contain references to more than one species.
4. There is clear evidence that in countries that have adopted enhanced disclosure measures patent applicants are readily able to include information on the origin and sources of materials concerned within patent applications.
5. The available evidence suggests that enhanced disclosure will become routine in the patent system as more countries adopt such measures. Enhanced disclosure will also multiple across the international patent system as countries adopt such measures through routes such as the Patent Cooperation Treaty.

Our analysis suggests that there is a need to improve disclosure in relation to revealing the sources of biodiversity in terms of baseline disclosure and the clarity and form of disclosure. We make five recommendations to improve the quality of disclosure and access to information on disclosure:

1. The European Patent Office as the main repository for global patent data should be invited to improve access to the whole text of patent documents.
2. Applicants should be encouraged to reference binomial Latin species names in conjunction with the country of origin or source of materials and traditional knowledge using standardized formats.
3. Limitations in access to the whole text of documents in multiple languages could be overcome by coding disclosure into the front page of electronic documents in patent databases using WIPO standardized two letter country codes and unique identifiers.
4. Existing taxonomic databases such as the ITIS & Species 2000 Catalogue of Life, the Global Biodiversity Information Facility and other taxonomic resources such as the Atlas of Living Australia should be used to develop an electronic index of patent documents containing biodiversity information to improve the visibility of biodiversity and transparency in access and benefit-sharing related disclosure.
5. WIPO could play an important role in coordinating improvements in the visibility of biodiversity and disclosure in patent information systems and assisting countries with developing effective enhanced disclosure systems.

4. Indigenous Peoples, Local Communities and Traditional Knowledge

"'Freedom from fear' could be said to sum up the whole philosophy of human rights" (Dag Hammarskjöld, 1956)

The problem of "biopiracy" or the misappropriation of biological resources and knowledge from indigenous peoples and local communities has been a significant focus of concern in debates on access and benefit-sharing. These concerns are reflected in the invitation by the Conference of the Parties of the CBD to the World Intellectual Property Organisation to provide assistance on this issue and the subsequent work of the WIPO IGC in developing work in this area. Within the CBD itself these concerns are reflected in the work of the Ad Hoc Working Group on Access to Genetic Resources and Benefit-Sharing in the elaboration of the international regime on access to genetic resources and benefit-sharing. Issues relating to indigenous peoples and local communities have also been a focus of debate at the United Nations Permanent Forum on Indigenous Issues and the Committee of the Convention on Economic and Social Cultural Rights. The 2007 United Nations Declaration on the Rights of Indigenous Peoples explicitly sets out the rights of indigenous peoples with respect to their knowledge, innovations and biological and genetic resources (see Box). In this section we focus on disclosure requirements and indigenous peoples and local communities in connection with traditional knowledge and genetic resources.

Article 31 United Nations Declaration on the Rights of Indigenous Peoples:

1. Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.
2. In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights.

In considering the relationship between indigenous peoples and local communities with respect to disclosure we adopted an empirical approach with the aim of casting additional light on this subject within the patent system. This work is exploratory rather than definitive and is intended to cast light on the nature of the issues involved.

Table 4.1 provides the results of searches of patent documents in Thomson Innovation using a range of terms that patent applicants are likely to use to describe traditional knowledge and indigenous peoples or local communities. As with the country data discussed above the tests were performed across all fields in the patent database and then progressively narrowed to target biodiversity. Family data refers to underlying filings while publications refer to the universe of subsequent publications in the period 1990-2010. The results were then text mined to explore the characteristics of traditional knowledge related terms.

Table 4.1: Exploring Indigenous Peoples and Traditional Knowledge in the Patent System 1990-2010

Search Terms	All Fields	Descriptions Only		Gated IPC Biodiversity Terms	
	Publications	Families	Publications	Families	Publications
aborigin*	618	316	569	171	321
amazonian*	135	68	130	49	91
american indian(s)	1,142	630	1,139	456	766
amerindian*	134	63	133	45	97
ayurveda/ayurvedic	1,349	652	1,249	449	867
chinese medicine(s)	33,933	3,949	5,887	2,199	3,305
ethnic group(s)	5,693	2,594	5,596	1,428	3,484
ethnics	22	12	21	8	12
ethnobotan*	290	123	289	110	252
ethnopharm*	1,801	831	1,786	643	1,340
first nation(s)	40	19	25	3	4
folk remedy/folk remedies	1,082	723	1,066	360	573
herbal remedy/herbal remedies	1,357	616	1,229	372	784
hunter gatherer(s)	73	43	73		
indian medicine(s)	169	78	169	58	108
indians	1,596	896	1,595	611	1,040
indigenous knowledge	6	3	6	1	2
indigenous medicine(s)	17	10	15	9	14
indigenous people(s)	143	85	143	41	68
indigenous population(s)	224	111	219	76	159
local knowledge	1,170	548	1,142	21	26
native american(s)	1,560	853	1,552	513	895
native people(s)	93	41	92	19	41
traditional knowledge	142	79	140	20	38
traditional medicine(s)	6,735	965	1,875	617	1,195
traditional remedy/ remedies	229	116	226	62	124
tribal*	1,041	512	982	91	131
tribe, (refined)	3,400	1851	3,286	1,146	2,142
tribe*	27,652	11,662	26,867	4,076	8,870
Note: * captures all possible variants of a root term i.e. aborigin* captures aborigines, aboriginal etc.					

In analysing these results two issues immediately came into focus. The first of these is that the top result for chinese medicine exposes a problem with language and access to data. Thus a search of all fields revealed a total of 33,933 results for chinese medicines. However, this is radically narrowed as the searches are confined to the description section of documents and then by biodiversity terms and classification codes. The reason for this is that the majority of these results originate from China and only the title and abstracts are available in English. In short, the results are affected by a lack of access to the whole texts of documents and the use of English terms. In contrast, we believe that the wider data for indian medicines or ayurvedic medicines is affected by the lack of access to patent data from India. In general data from India will refer only to information that has entered the international system or the main patent offices.

A second problem is exposed by efforts to capture all uses of the term tribe (tribe*). At first sight this data might be interpreted as suggesting that the term refers to indigenous peoples. In practice, text mining of the data revealed that the dominant use of this term is as a taxonomic category (i.e. tribe Jollifieae or Maydeae) or as a component of compound or a wide range of other names. Indeed, tribe proved to be a remarkably noisy term when all possible conjugations were accounted for. A refined approach focusing on specific terms (tribe, tribal, tribeswoman etc.) radically reduced the results to 3,400 results overall and 2,142 results confined to a sample for biodiversity. However, the term tribe as a taxonomic category remained as a major issue.

Other terms, such as "first nation" (which exclusively refers to the first nation to perform an action) or "indian" (typically referring to citizens of India or persons of indian origin) reveal the problem that terms may have multiple uses.

The problem here is that while indigenous peoples and traditional knowledge are certainly present in the patent system, pinpointing the data with accuracy is extremely time consuming and fraught with difficulty. The issues encountered are in fact similar to those encountered with countries in terms of clarity of disclosure. However, the situation is made more difficult by the following factors:

1. It is at the discretion of applicants whether the origins of knowledge and materials from indigenous peoples or local communities are referenced in applications.
2. Patent applicants may use a wide variety of terms to describe material or knowledge originating from indigenous peoples, local communities or traditional knowledge.
3. The terms used may have multiple uses (i.e. tribe as a taxonomic category). If taken at face value this can give a very misleading impression of activity.

The main conclusion that can be drawn from this data is that indigenous peoples and long established written traditions of traditional medicines (i.e. China and India) are certainly present in the patent system. The problem is a lack of clarity in disclosure.

When viewed from a perspective that takes into account the concerns of indigenous peoples the main issue here is uncertainty. That is, it is very difficult for indigenous peoples' authorities or organisations to be certain whether patent activity is or is not taking place. This produces uncertainty about whether material and knowledge originating with indigenous peoples is the subject of patent protection. This uncertainty can contribute to a climate of fear. This raises the question of how certainty could be improved for indigenous peoples and government authorities with responsibility for ensuring compliance with relevant legislation and regulations.

The Relationship between Genetic Resources and Traditional Knowledge:

The relationship between genetic resources and the knowledge, innovations and practices of indigenous peoples and local communities has been an important subject of debate on access to genetic resources and benefit-sharing. A key focus of this debate has been whether indigenous peoples knowledge, innovations and practices are "associated with genetic resources" or whether the appropriate use of terms is "genetic resources and associated traditional knowledge". The former approach seeks to confine the rights of indigenous peoples to circumstances where their knowledge is associated with a genetic resource and, as in the Andean legislation, to limit rights to "knowledge" rather than the genetic resource per se (which may be reserved to the state). In reality, the separation of knowledge from a

resource is wrong headed because it fails to recognize that it is knowledge that transforms genetic or biological material into a resource useful for human purposes. That knowledge may be drawn from a variety of sources or combinations of sources, but in the realm of biology knowledge is the key ingredient in the transformation of material into a resource. The second approach is broader and does a better job of capturing the relationship between genetic resources and knowledge in the specific case of the knowledge, innovations and practices of indigenous and local communities.

A basic insight into the combinations and recombinations of knowledge involved in creating resources is provided by examining the International Patent Classification (IPC) codes that are applied to the data presented in Table 4.1. IPC codes provide a description of the contents of applications and are used to identify sectors of activity for statistical purposes. Table 4.2 provides the results of sectioning selected data using these codes to identify biotechnology related patent activity and activity for a range of sectors. The sector classification is based on the IPC sub-class category and is indicative rather than definitive. Additional data is provided for plant based medicines (A61K36) drawing on the country level data discussed in section 3.

Table 4.2: Indigenous Peoples and Traditional Knowledge by Sector of Activity

	Gated IPC Biodiversity Terms		Sector Classifications (IPC)				
Search Terms	**Families**	**Publications**	**Biotech**	**Agriculture**	**Medicines**	**Foodstuffs**	**Cosmetics**
aborigin*	171	321	161	44	164	29	21
amazonian*	49	91	41	11	64	4	14
american indian(s)	456	766	533	41	316	26	17
amerindian*	45	97	72		46		
Ayurveda/ ayurvedic	449	867	90	76	755	121	76
chinese medicine(s)	2,199	3,305	565	188	2,679	761	433
ethnopharm*	643	1,340	105	80	903	91	3
folk remedy/folk remedies	360	573	62	39	352	162	74
herbal remedy/ remedies	372	784	84	36	668	106	27
native american(s)	513	895	531	61	406	28	10
traditional medicine(s)	617	1,195	172	87	1,016	123	68
tribal*	91	131					
tribe revised query	1,146	2,142	1,069	1,314	360	92	22
A61K36 (1)	5,850	10,893	1,221	800	10,116	3,309	2,359

Notes: (1) Refers to a sample of data for plant based medicines with descriptions from the main jurisdictions.

In considering these results it becomes apparent that biotechnology based approaches (approaches involving biochemistry, genetic engineering, DNA, RNA and amino acids and peptides) are present across the spectrum of the data. This reflects the growing accessibility of biotechnology based approaches and their application to natural products. This finding is

reinforced by data from plant based medicines (A61K36) where biotechnology based approaches began to gather pace from the late 1990s onwards.

However, interpretation of the data with respect to biotechnology is affected by research on indigenous peoples and health focused genomics research. Thus, references to american indians or native americans frequently refer to the results of genetics related research and comparative genomics. This includes references to the results of research in relation to diabetes, the Strong Heart Study of the prevalence and risk factors for coronary disease among native americans, genetic polymorphisms associated with particular diseases, biomarkers, haplotypes and ancestry studies.

As this makes clear, in contrast with the analysis of the country of origin or source of genetic material in the case of indigenous peoples, their genetic make up may form part of the substance of patent applications. Indigenous peoples organisations and indigenous scholars have raised a range of concerns about human genetic research with respect to ethics and human rights.[97] In debates on the international regime on access to genetic resources and benefit-sharing, in line with previous COP decisions, it appears likely that human genetic resources will not fall into the scope of the international regime. These issues will not therefore be considered further here.

Rather, the question becomes how the presence of indigenous peoples and traditional knowledge might be made more visible in the international patent system and the potential contribution of enhanced disclosure measures to this process. In considering this issue we turn once again to lessons learned from the disclosure requirement under the Bayh-Dole Act.

As an experiment we compared the publication numbers of the patents in our sample data for indigenous peoples and traditional knowledge with the 18,689 publication numbers from the Bayh-Dole disclosure data for biodiversity discussed in Section 2. The results of this exercise are presented in Table 4.3.

Table 4.3: Bayh-Dole disclosure and Indigenous Peoples and Traditional Knowledge (sample data)

Themes	Total Publications	Bayh-Dole Disclosure	
		Families	Publications
native american	895	17	27
ethnopharm	1340	13	33
traditional medicine(s)	1197	11	14
tribe revised	2142	10	33
american indian(s)	766	9	21
aborigin*	321	6	8
chinese medicine(s)	3305	6	7
herbal remedy/remedies	784	6	9
amerindian(s)	97	2	2
ayurveda/ayurvedic	868	2	2
folk remedy/remedies	573	2	5
tribal*	131	2	2
amazonian(s)	91	1	1

As can be seen from Table 4.4 the overall scores are low. However, this provides proof of concept that the introduction of a disclosure statement into patent applications would

facilitate monitoring of patent activity for indigenous peoples and traditional knowledge. This would also permit the identification of the applicants, the species involved and the tracking of patent activity worldwide.

Conclusions: Advancing Disclosure for Indigenous Peoples and Traditional Knowledge:

The difficulties involved in interrogating disclosure of indigenous peoples and traditional knowledge within the patent system are similar to the problems encountered with country names discussed in section 3. This includes uncertainty regarding whether relevant indigenous peoples from whom resources and knowledge are being sourced are disclosed at all. Where there is disclosure disentangling the indigenous peoples concerned proves difficult because of the wide range of possible uses of particular terms. How might these problems be addressed?

First, as with country level information, patent applicants could be required to enhance the clarity of disclosure of the origin of genetic resources and traditional knowledge within patent applications. Specifically, they could be asked to disclose the name of the ethnolinguistic group (or people) concerned. All indigenous peoples have names (Shuar, Yanomami, Piaroa, Maori etc) and these names frequently coincide with languages names. A requirement to name the people concerned using ethnolinguistic names could then be matched against indexes of indigenous peoples/ethnolinguistic group names.

A number of language lists are available on the national and the international level. On the country level the Australian Institute of Aboriginal and Torres Straits Islander Studies (AIATSIS) has developed a list of names of aboriginal languages and their synonyms in Australia. Many countries also use language lists as part of national census exercises, particularly in countries where the existence of indigenous peoples is recognised. On the global level, the *Ethnologue Catalogue* contains a list of the world's languages by country and forms the basis for an international standard for naming languages. The Summer Institute of Linguistics has established an international standard (ISO 639-3) for global language names using the information in the Ethnologue Catalogue. The use of such match lists in patent information systems would facilitate retrieval of patent data of relevance to indigenous peoples.

As discussed above, as part of access and benefit-arrangements a requirement could be introduced to include a statement on access and benefit-sharing in the description section of patent applications. The terms and conditions for the inclusion of such a statement could stipulate the need to include reference to the indigenous and local communities concerned, relevant terms and conditions, and could potentially be linked to an international certificate. Relevant information in the statement could then be coded in patent databases to make document retrieval easier with minimal, if any, implications for patent examiners.

At issue here is the desirability of improving the visibility of indigenous and local communities and traditional knowledge within the patent system and enhancing certainty for indigenous and local community authorities that the terms of access and benefit-sharing agreements are being complied with. In our view this could be addressed through a general requirement to name the indigenous and local communities concerned at the level of ethnolinguistic groups, the terms and conditions of access and benefit-sharing agreements and the use of existing electronic information systems and resources.

5. Conclusions:

Disclosure requirements have become an increasing focus of debate under the Convention on Biological Diversity, the World Intellectual Property Organisation and the TRIPS Council of the World Trade Organisation. However, debate on disclosure of the origin or source of genetic resources and the traditional knowledge of indigenous and local communities has become stuck in a vicious cycle of inaction. It is time to move on.

The fundamental long term purpose of the international system is the disclosure of new and useful inventions that become widely available for public use following the temporary period of protection provided by patents. Debates on disclosure of origin within patent applications tend to focus on the *consequences* of disclosure for rights holders. In the process the wider benefits of disclosure have been obscured from view. That is, enhanced disclosure would contribute to increased legal certainty for providers and users of genetic resources and traditional knowledge involved in access and benefit-sharing agreements. At the same time, enhanced disclosure would serve the long term objectives of the Convention on Biological Diversity by making the contribution of biodiversity and traditional knowledge to science and innovation more widely visible. In the process, public and policy understanding of the importance of biodiversity for science and innovation would grow.

An increasing number of countries have now adopted enhanced disclosure requirements for genetic resources and traditional knowledge in support of the third objective of the Convention on Biological Diversity. The practical consequence of the adoption of enhanced disclosure requirements is that disclosure will inevitably multiply across the international patent system under the Patent Cooperation Treaty and regional patent instruments. Experience from the United States reveals that it is sufficient to identify disclosure in one patent document to be able to track that document as it multiplies around the world. The patent system is already configured to permit such tracking through the family number system.

Analysis of experience in countries where enhanced disclosure measures have already been adopted revealed the following key issues focusing on *improving transparency* and *information retrieval* in patent documents:

1. *A need to improve access to global patent data*. Efforts to provide greater electronic access to the whole text of patent documents should be promoted by patent offices as part of the wider disclosure function of the patent system.
2. *Use of patent information systems*. The growing availability of electronic patent information provides pathways to enhancing the visibility of disclosure and biodiversity to science, society and policy makers. The European Patent Office as the global repository of patent data for public use and statistical purposes has a key role to play in cost effective measures to improve the visibility of biodiversity within the international patent system.
3. *Clarity and Form of Disclosure*. Guidance could be provided to applicants on the clarity and form of disclosure on the source of species and components within patent applications. This should include greater attention to the form of species names and geographic information to facilitate retrieval of information on biodiversity from patent databases.
4. *A Statement on Access and Benefit-Sharing in Patent Applications*. Countries may wish to include a requirement for a statement on access and benefit-sharing in the description sections of any patent applications and reporting on IPR rights to the relevant government agency. The ABS statement could include references to the contract, permit or license number, the relevant government agency, a certificate number (where appropriate),

geographic information, information on indigenous and local communities and terms and conditions. The information will preferably be provided in a form that can be retrieved in electronic information systems and coded into the front page of electronic patent documents. The Patent Law Treaty (PLT) provides a basic model form that could be used or modified for this purpose.

5. *Use of Taxonomic Information*. The visibility of biodiversity within the patent system could be improved by using lists of species held in taxonomic databases such as the Species 2000 & ITIS *Catalogue of Life* and the Global Biodiversity Information Facility (GBIF). Taxonomic databases include information on families, genera, species and the distribution of species that could be used to index the patent literature to improve the visibility of biodiversity and associated traditional know\ledge. Such lists could be annexed to the International Patent Classification.
6. *Use of Ethnolinguistic Information*. The contribution of indigenous and local communities to science and innovation could be made visible through the use of lists of languages such as the *Ethnologue* catalogue of the world's linguistic diversity. Such lists could be used to index patent data and improve certainty for indigenous and local communities on whether the terms and conditions of access and benefit-sharing arrangements are being respected.
7. *Visibility and Coding in Patent Databases*. Disclosure information, notably a statement on access and benefit-sharing could be coded into the front page of patent records in patent databases. This could be achieved using existing standard two letter country codes and numeric identifiers and be included in the existing citations field in patent databases.

Appendix
Bayh-Dole Disclosure Requirement Data Comparisons

The following information is provided to aid researchers interested in identifying Bayh-Dole disclosure in United States Patent Applications and Grants. The data shows original workings (unadjusted) for a range of search terms used in Thomson Innovation in the US patent applications and grants whole text data for publication years 1990-2010. Following text mining on the results the second table shows adjusted data to accommodate numerous references to "not applicable" or "n/a" under this heading within United States applications and grants.

Unadjusted Test Queries United States Applications and Grants 1990-2010

	Text Fields	Description	Government Interest Field (Thomson)
Large query (note 54)	138,625	83,300	55,403
"Federally Sponsored" or "government has certain rights" or "this invention was made with government support"	119,454	78,586	40,929
(Federally sponsored) AND (Research OR Development)	84,752	72,493	12,237

Adjusted Text Queries for Federally Sponsored Research in United States Patent Applications and Grants Excluding "not applicable" or "n/a" in whole text

	All Fields	Description	Government Interest Field (Thomson)
Large query (note 54 below)	69,002	18,777	54,870
"Federally Sponsored" or "government has certain rights" or "this invention was made with government support"	51,455	17,783	40,411
(Federally sponsored) AND (Research OR Development)	19,335	9,327	11,720

The large query used in the searches referenced in the tables above was as follows.

"Federally Sponsored" OR "federal sponsorship" OR "government support" OR "government contract" OR "government funding" OR "government funded" OR "government supported" OR "government sponsored" OR "governmental interest" OR "government interest" OR "government interests" OR "government rights" OR "governmental rights" OR "government right" OR "certain rights in the invention" OR "certain rights in this invention" OR "Government may have certain rights in this disclosure" OR "Government may have certain rights in the disclosure" OR "certain rights in the disclosed invention" OR "FEDERAL FUNDING STATEMENT" OR "statement regarding federal rights" OR "statement regarding government rights" OR "Statement of government interests" OR "statement of government interest" OR "Statement as to Rights to Inventions"

Endnotes

[1] These are the authors' personal views and not necessarily those of the IAS or Cesagen. Research at the ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) was funded by the UK Economic and Social Research Council (ESRC).

[2] "44 (n) Promote the wide implementation of and continued work on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization of the Convention, as an input to assist Parties to the Convention when developing and drafting legislative, administrative or policy measures on access and benefit-sharing, and contract and other arrangements under mutually agreed terms for access and benefit-sharing;

(o) Negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources;

(p) Encourage successful conclusion of existing processes under the World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, and in the ad hoc open-ended working group on article 8 (j) and related provisions of the Convention;

(q) Promote practicable measures for access to the results and benefits arising from biotechnologies based upon genetic resources, in accordance with articles 15 and 19 of the Convention, including through enhanced scientific and technical cooperation on biotechnology and biosafety, including the exchange of experts, training human resources and developing research-oriented institutional capacities;

(r) With a view to enhancing synergy and mutual supportiveness, taking into account the decisions under the relevant agreements, promote the discussions, without prejudging their outcome, with regard to the relationships between the Convention and agreements related to international trade and intellectual property rights, as outlined in the Doha Ministerial Declaration;

[3] Adopted by UN General Assembly Resolution 57/253, in February 2003, endorsing both the *Johannesburg Declaration on Sustainable Development* and the *Plan of Implementation.*

[4] Article 1 'The objectives of this Convention … are…the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources…"

[5] Page 99, *Gene Cartels: Biotech Patents in the Age of Free Trade,* Luigi Palombi Pub: Edward Elgar, 2009. This book contains an informative guide to the history of the development of the patent system.

[6] See WIPO PCT/R/WG/4/13, Proposals by Switzerland Regarding Declarations of the Source of Genetic Resources and Traditional Knowledge in Patent Applications. Would introduce a new paragraph at (g) that would allow national law to require in accordance with PCT 27(1) applicants to declare:

(i) the source of specific genetic resources for inventions directly based on such resources or that the source is unknown; and

(ii) the source of traditional knowledge for inventions directly based on such resources or that the source is unknown.

It also sought to amend PCT Rule 4.17 to allow parties to include such declarations at the international stage of PCT applications.

[7]. Burton, personal conversations with Brazilian officials in Sao Paulo in late 2009.

[8] Sarnoff, J.D. and Correa, C.M. (2005) Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications. United Nations Conference on Trade and Development. UNCTAD/DITC/TED/2005/14. Also available as UNEP/CBD/WG-ABS/4/INF/2.

[9] Permission to cite this advice currently pending.

[10] Regulations Under the Patent Law Treaty, as in force from January 1, 2006. http://www.wipo.int/treaties/en/ip/plt/trtdocs_wo039.html#P229_41353. Accessed 02/08/2010.

[11] The central patent database is known as Documentation Database (DOCDB). For information on EPO data sources see http://www.epo.org/patents/patent-information/raw-data.html

[12] Boettiger, S & Bennett, A (2006) Bayh-Dole: if we knew then what we know now. *Nature Biotechnology*, Vol 24 (3): 320-323. Citation at 320. Rai, A. and Eisenberg, R. (2003) 'Bayh-Dole Reform and the Progress of Biomedicine', *Law and Contemporary Social Problems*, 66: 289–314.

[13] Oldham, P (2004) Global Status and Trends in Intellectual Property Claims: Microorganisms. Global Status and Trends in Intellectual Property Claims. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1331510

[14] Technology Transfer Commercialization Act of 2000. Public Law 106-404-Nov. 1

[15] OECD (2003) *Turning Science into Business: Patenting and Licensing at Public Research Organisations*. Paris: Organisation for Economic Co-operation and Development.

[16] South Africa adopted the Intellectual Property Rights from Publicly Financed Research and Development Act in 2008 and entered into force in 2010. In India, The Protection and Utilization of Public Funded Intellectual Property Bill, 2008 remains under consideration.
[17] The Economist "Innovation's golden goose' The Economist, Dec 14, 2002. Vol. 365 Iss. 8303, pg 3
[18] See Boettiger and Bennett. Include reference to Eisenberg on Patent Swords and Shields.
[19] See for example, NIH (1998) Report of the National Institutes of Health (NIH) Working Group on Research Tools. June 4 1998. See also the US Secretary's Advisory Committee on Genetics, Health and Society 2010 Report on Gene Patents and Licensing Practices and Their Impact on Patient Genetics, Heath, and Society discussed in the main body of the text.
[20] Heller, M and Eisenberg, R (1998) Can Patents Deter Innovation? The Anticommons in Biomedical Research. *Science* 1998; 280: 698-701.
[21] See Boettiger and Bennett (2006) at note 12.
[22] So AD, Sampat BN, Rai AK, Cook-Deegan R, Reichman JH, et al. (2008) Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience. PLoS Biol 6(10): e262. doi:10.1371/journal.pbio.0060262
[23] As highlighted by Boettiger and Bennett (2006), the Bayh-Dole Act began life as a small amendment (P.L96-517) to the United States Patent and Trademark Act. See note 12.
[24] For a full listing of the provisions of Chapter 18 of USC 35 see http://www.law.cornell.edu/uscode/uscode35/usc_sup_01_35_10_II_20_18.html
[25] The case was disputed with respect to the written description requirement. That is, University of Rochester asserted that Searle (collectively Pfizer) had infringed a grant on a COX2 inhibitor with Searle successfully appealing on the grounds that the written description requirement for patentability had not been met for the claimed COX2 inhibitor in the University of Rochester patent specification. Therefore one skilled in the art could not practice the claimed invention. See, University of Rochester v. Searle et al. Court of Appeals for the Federal Circuit 385 F. 3d 916 (2004). We have drawn here on the very useful Wikipedia entry for the Bayh-Dole Act http://en.wikipedia.org/wiki/Bayh–Dole_Act
[26] Provided, That any such information as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.
[27] Provided, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production.
[28] These provisions are subject to an appeals procedure.
[29] Chapter 29 of USC 35 is concerned with Remedies for Infringement of Patent, and Other Actions.
[30] See also USC Title 5 Government Organization and Employees at 552 on Public information; agency rules, opinions, orders, records, and proceedings.
[31] In the context of access and benefit-sharing it should be noted that this requirement does not apply to inventions arising from a Cooperative Research and Development Agreement (CRADA) under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (12 USC 3710a). Note that CRADAs advocate exclusive licensing http://www.law.cornell.edu/uscode/html/uscode15/usc_sec_15_00003710---a000-.html
[32] http://law.justia.com/us/cfr/title37/37cfr401_main_02.html
[33] Government Accountability Office (2009) *Federal Research: Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions*. United States Government Accountability Office, July 2009. GAO-09-742. Citation at 4-5.
[34] http://law.justia.com/us/cfr/title37/37cfr1_main_02.html
[35] Under the amendment to the Patent and Trademark Act the General Accounting Office was charged with periodic reporting and released a report on university licensing of inventions in 1991, followed by a report on administration of the Bayh-Dole Act by Research Universities in 1998.
[36] General Accounting Office (1999) *Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision*, August 1999, GAO/RCED-99-242, 2.
[37] Ibid. 2
[38] Ibid. 2
[39] Ibid. 6
[40] Ibid. 6
[41] Ibid. 6
[42] iEdison https://s-edison.info.nih.gov/iEdison/
[43] http://era.nih.gov/ProjectMgmt/iedison2/index.cfm
[44] Technology Transfer Commercialization Act of 2000. Public Law 106-404-Nov. 1

[45] General Accounting Office (2002) *Intellectual Property: Federal Agency Efforts in Transferring and Reporting New Technology*, October 2002, GAO-03-47, 29.
[46] Government Accountability Office (2009) *Federal Research: Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions*. July 2009. GAO-09-742. It may be noted that, at the time of writing, GAO oversight has been discontinued through a failure to provide budget provision for reporting.
[47] Ibid. 9
[48] Ibid. 10
[49] Ibid. 10
[50] Ibid. 14
[51] Ibid. 14
[52] Rai, A and Eisenberg, R (2003) Bayh-Dole Reform and the Progress of Biomedicine. Law and Contemporary Social Problems. Winter/Spring 2003; 66: 289-314 http://www.law.duke.edu/journals/66LCPRai.
[53] CellPro petition to Donna E. Shalala, Secretary, Department of Health and Human Services, March 2 1997.
[54] National Institutes of Health, Office of the Director. Determination in the Case of Petition of Cellpro, Inc. August 1st 1997.
[55] Ibid. 8
[56] National Institutes of Health, Office of the Director. In the case of NORVIR Manufactured by Abbott Laboratories Inc. July 2nd 2004. http://www.ott.nih.gov/policy/March-in-norvir.pdf
[57] National Institutes of Health, Office of the Director. In the Case of Xalatan Manufactured by Pfizer, Inc. September 1st 2004. http://www.ott.nih.gov/policy/March-in-xalatan.pdf
[58] Campbell Plastics Engineering & MFG Inc v. Brownlee. Court of Appeals for the Federal Circuit 389 F.3d 1243,
[59] See chapter 5 on Academic Research: Article and Patents. Appendix Table 5-47. http://www.nsf.gov/statistics/seind10/c5/c5s4.htm#s5
[60] National Science Board (2010) Science and Engineering Indicators 2010. Arlington, VA: National Science Foundation (NSB 10-01)
[61] CRADA = Cooperative Research and Development Agreement; DOC = Department of Commerce; DOD = Department of Defense; DOE = Department of Energy; HHS = Department of Health and Human Services; NASA = National Aeronautics and Space Administration; USDA = U.S. Department of Agriculture

NOTES: Other federal agencies not listed but included in total: Department of the Interior, Department of Transportation, Department of Veterans Affairs, and Environmental Protection Agency. Department of Homeland Security expected to provide technology transfer statistics starting in FY 2008. Invention licenses refers to inventions that are/could be patented. Other intellectual property refers to intellectual property protected through mechanisms other than a patent, e.g., copyright. Total active CRADAs refers to agreements executed under CRADA authority (15 U.S.C. 3710a). Traditional CRADAs are collaborative R&D partnerships between a federal laboratory and one or more nonfederal organizations. Federal agencies have varying authorities for other kinds of collaborative R&D relationships.

SOURCE: National Institute of Standards and Technology, Federal Laboratory Technology Transfer, Fiscal Year 2007, Summary Report to the President and the Congress, January 2009, http://patapsco.nist.gov/ts/220/external/index.htm, accessed 6 May 2009. See appendix table 4-43.

Science and Engineering Indicators 2010. Table 4-22 Federal technology transfer activity indicators, by selected U.S. agency: FY 2007.
[62] National Institute of Standards and Technology (2010) *Federal Laboratory Technology Transfer Fiscal Year 2008: Summary Report to the President and the Congress*. U.S. Department of Commerce. March 2010. See Table 5 Pages 15-16.
[63] National Science Board (2010) Science and Technology Indicators 2010. Arlington, VA: National Science Foundation (NSB 10-01). See Chapter 5 on Academic Research and Development, section on Outputs of S&E Research: Articles and Patents reporting that many technology transfer offices report negative income.
[64] Ibid.
[65] National Institutes of Health (2010) Annual Report Fiscal Year 2009. U.S Department of Health & Human Services, National Institutes of Health, Office of Technology Transfer. NIH 2010: 3.
[66] National Institutes of Health (2010) Annual Report Fiscal Year 2009. U.S Department of Health & Human Services, National Institutes of Health, Office of Technology Transfer. Citation at 4.
[67] Search Queries: 1. "Federally Sponsored" or "government has certain rights" or "this invention was made with government support" NOT "not applicable" or n/a". 2) "family" or "genus" or "species" or "plant extract" or "natural extract" or "genome" or "synthetic biology" or "synthetic genomics" or "metabolic engineering". 3) (A01H) OR (A01K) OR (A01N) OR (A23B) OR (A23C) OR (A23D) OR (A23F) OR (A23G) OR (A23J) OR (A23K) OR (A23L) OR (A24B) OR (A24D) OR (A61K) OR (A61L) OR (A62D) OR (B01D) OR (B01F) OR (B01J) OR (B09C) OR

(C02F) OR (C04B) OR (C05F) OR (C07C) OR (C07D) OR (C07G) OR (C07H) OR (C07J) OR (C07K) OR (C08B) OR (C08C) OR (C08F) OR (C08G) OR (C08H) OR (C08L) OR (C09B) OR (C09D) OR (C09F) OR (C09H) OR (C09J) OR (C09K) OR (C11B) OR (C11C) OR (C11D) OR (C12G) OR (C12M) OR (C12N) OR (C12P) OR (C12Q) OR (C12R) OR (C12S) OR (C22B) OR (C40B) OR (C99Z) OR (D01F) OR (D06L) OR (D06M) OR (D06P) OR (D21H) OR (G01N) OR (G06N) OR (G09B) OR (G11C) OR (G21F) OR (H01M)

[68] The European Patent Office public esp@cenet database provides access to the whole text of available patent documents from around the world. In cases where the whole text is not available in one jurisdiction the system presents the whole text of the equivalent family member. This feature of existing information technology provides a possible way forward in monitoring of disclosure across multiple jurisdictions.

[69] http://www.wipo.int/pct/guide/en/gdvol1/annexes/annexk/ax_k.pdf

[70] A limitation of this approach is that it will only capture two word references to species names rather than variants i.e. E. coli or genus references to Escherichia or common names.

[71] Supra note 22.

[72] Oldham, P (2009) An Access and Benefit-Sharing Commons: The Role of Commons/Open Source Models in an International Regime on Access to Genetic Resources and Benefit-Sharing.

[73] OECD (2009) OECD Patent Statistics Manual. Organisation for Economic Co-operation and Development.

[74] Webb, C., H, Dernis and D, Harhoff and K, Hoisl (2005) Analyzing European and International Patent Citations: A set of EPO Patent Database Building Blocks. STI Working Paper 2005/9. Statistical Analysis of Science, Technology and Industry. Paris: OECD. <http://www.oecd.org/dataoecd/18/17/35520805.pdf>.

[75] National Science Board (2010) Science and Technology Indicators 2010. Arlington, VA: National Science Foundation (NSB 10-01). See Chapter 5 on Academic Research and Development, section on Outputs of S&E Research: Articles and Patents reporting that many technology transfer offices report negative income.

[76] For details of the case see the Public Patent Foundation Website: http://www.pubpat.org/warfstemcell.htm

[77] NIH (2005) Best Practices for the Licensing of Genomic Inventions. Department of Health and Human Services, National Institutes of Health. http://www.ott.nih.gov/policy/lic_gen.html#best

[78] ALRC. Genes and Ingenuity: Gene Patenting and Human Health. June 2004. Australia: SOS Printing Group, http://www.austlii.edu.au/au/other/alrc/publications/reports/99/index.html.

[79] OECD (2006) Guidelines for Licensing of Genetic Inventions. Paris: Organisation for Economic Co-operation and Development. http://www.oecd.org/dataoecd/39/38/36198812.pdf

[80] National Research Council (2006). Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health. Merrill, S.A and Marza, A-M. (eds.). Washington, D.C.: National Academies Press.

[81] Secretary's Advisory Committee on Genetics, Health, and Society (2010) *Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests.* Citation at 93.

[82] For wider discussion on the subject of certificates see Tobin, B, Burton, G and Fernandez-Ugalde, J.C. (2008) Certificates of Clarity or Confusion: The search for a practical, feasible and cost effective system for certifying compliance with PIC and MAT. Yokohama, Japan: United Nations University, Institute for Advanced Study

[83] There is an extensive literature on the subject of technology and knowledge spillovers See generally Jaffe, A. B . and Trajtenberg (2002) *Patents, Citations & Innovations: A Window on the Knowledge Economy*. Cambridge, Mass.: Massachusetts Institute of Technology.

[84] See the important technical study prepared by the Secretariat of WIPO for the Seventh Conference of the Parties of the Convention on Biological Diversity. WIPO Draft Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge. UNEP/CBD/COP/7/INF/17 and WO/GA/30/7 Add. 1. A second draft was prepared as WIPO/IP/GR/05/3 entitled Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications Second Draft.

[85] At its Sixteenth session the WIPO IGC considered a range of country reports on disclosure measures. These documents are available via the WIPO website with titles beginning @Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources at http://www.wipo.int/meetings/en/details.jsp?meeting_id=20162

[86] Hoare, A and Tarasofsky, R (2006) Disclosure of Origin in IPR Applications: Options and Perspectives of Users and Providers of Genetic Resources. London: Chatham House.

[87] WIPO/GRTKF/IC/2/15 Patents Using Biological Sources Material (I) and Mention of the Country of Origin in Patents Using Biological Source Material (II). Submission by the Delegation of Spain. December 13, 2001.

[88] Oldham, P and Hall, S (2009) A European Patent Indicator for Access to Genetic Resources and Benefit-Sharing. Report to the European Environment Agency EEA/BSS/08/12.

[89] In practice the whole text of patent applications and accompanying disclosure will typically be accessible where an application is also submitted through a regional instrument (such as the European Patent Convention) or the international Patent Cooperation Treaty.

[90] A total of 31,849 patent documents containing classification code A16K36 and A61K3578 were published in the main jurisdictions between 1990 and January 2010. Our sample from October 2009, captures 93.4% of activity in the main jurisdictions. Worldwide a total of 89,822 publications are recorded in Thomson Innovation with our sample representing 33%. However, the full texts of these wider documents are not accessible.
[91] This code was formally a lower level code A61K35/78. With the introduction of code A61K36 patent offices such as the European Patent Office, reclassified their collections. This reveals that retrospective reclassification of patent library collections is possible. However, there are limitations to reclassification. Thus, not all documents classified as A61K35/78 were reclassified with the new code A61K36 for reasons that are presently unclear. Only A61K36 is recorded in PATSTAT. In contrast text mining data in our sample includes the historic A61K35/78.
[92] Context words were selected based on a review of terms appearing in the documents in Word Smith to capture roots of multivariant terms. The query used was 'collect*/origin*/source*/from/indigen*/nativ*/tradit*/grow*/obtain*/occur*/cultiv*/' with * as a wildcard capturing variants of the root. Note that the number of context words that may be used in Word Smith is limited.
[93] When a patent application is filed for the first time it is awarded a priority number as a unique identifier under the terms of the Paris Convention. Priority filings therefore refer to first filings of applications in a particular country.
[94] Notes: 1) Refers to patent documents containing a relevant priority country code between 1990-2010 where counts refer to publications. 2) Raw publication counts for searches commencing the year following the date of adoption of legislation i.e. adopted 2000 = search by priority year 2001-2010. 3) Refers to International Patent Classification codes on the sub-class level... see Oldham 2007 and Oldham & Hall 2009. 4) Restricted to documents containing a description. * Venezuela was formerly a member of the Andean Pact. Data on disclosure measures is based on reports to the 16th Session of the WIPO IGC accessible at http://www.wipo.int/meetings/en/details.jsp?meeting_id=20162
[95] See WIPO (2010) World Intellectual Property Indicators, 2010 Edition. World Intellectual Property Organization.
[96] Of the 13,630 documents with descriptions 16,627 documents were available for download.
[97] For example see, Tsosie, R (2007) 'Cultural Challenges to Biotechnology: Native American Genetic Resources and the Concept of Cultural Harm,'Journal of Law, Medicine and Ethics, Vol. 35: 396-411.