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Patent Claims on Genetic Resources of Secret Origin

Disclosure Data from Recent International Patent Applications with Related Deposits under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

by
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I INTRODUCTION

This is a study of recent international patent applications under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. It finds that in an important patent class for genetic resource patents, three quarters of applicants do not disclose the country of origin of genetic resources that appear in their claims. In those patent applications in which disclosure was made (one quarter of the total), in nearly two thirds of cases the applicant and the genetic resource were from the same country. More rarely, patent applicants identified a foreign country as the origin of a claimed genetic resource.

The study did not find significant correlation between ratification of the Convention on Biological Diversity (CBD) and disclosure of origin of genetic resources in patent applications. This suggests that accession to the CBD by the home country of a patent applicant is often in itself insufficient incentive to corporations to prompt disclosure of the origin of genetic resources that they claim. Indeed, patent applicants in the European Union (EU), whose members have all ratified the CBD, were the poorest performing regional group. In the study sample, EU companies divulged the origin of genetic resources only 17% of the time.

The strict secrecy that surrounds deposits of biological materials made under the Budapest Treaty impairs gathering data on implementation of the CBD's requirements for access and benefit sharing, hindering development of a more detailed picture of disclosure practices.

This study's conclusions support the goal of many developing countries that disclosure of origin of genetic resources in patent applications should be required, and indicate that international measures beyond the CBD and its Nagoya Protocol on access and benefit sharing[1] are necessary to ensure patent procedures capable of reliably identifying cases of possible misappropriation, so that appropriate resolution procedures can be invoked.

[1] The Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity was concluded in 2010 and awaits 50 ratifications by CBD Parties to enter into force.

II BACKGROUND

Since the emergence of life patenting in the late 1980s, biopiracy has been a matter of international public concern, particularly in biodiverse developing countries. Biopiracy cases frequently involve Northern corporations or other entities, such as universities, making intellectual property claims over genetic resources and/or associated traditional knowledge without the prior informed consent (PIC) and mutually agreed terms (MAT) with the rightful owners of those resources and knowledge.

As a result, disclosure of origin of genetic resources in intellectual property applications has been on the intergovernmental agenda for years, beginning in the negotiation of the CBD (completed in 1992) and the Nagoya Protocol on access and benefit sharing under the CBD (completed in 2010). Since 2000, there have been lengthy discussions at the World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO IGC).

At the IGC, developing countries generally support the establishment of mandatory disclosure requirements that will oblige patent claimants to reveal, in patent applications, where they obtain genetic resources that they claim. On the other side, some developed countries deny any need for such rules and resist movement towards their establishment. Other developed countries, including the European Union, favor much weaker disclosure requirements than those sought by developing countries.

At the time of writing, the IGC has developed a draft text on disclosure, however, it is not clear if this text will advance to a diplomatic conference intended to formalize it into an agreement.[2]

A long lineage of biopiracy cases has demonstrated that patent applicants often do not disclose the origin of genetic resources thereby hiding misappropriation of genetic resources and associated traditional knowledge.

Despite the lengthy debate on disclosure of origin, little data has been compiled on the frequency of actual disclosure in patent applications, irrespective of the country of origin of the genetic resources claimed. In other words, the background rate of disclosure in international patent applications is ill-documented, as is what this may reveal about current practices, and what it suggests for the debate over disclosure at WIPO, the CBD, and elsewhere.

To begin to answer these questions, this study assesses disclosure of origin by analyzing recent international patent applications with associated deposits of biological materials made under the Budapest Treaty.

The Budapest Treaty was completed in 1977. It creates an international union among Contracting Parties for the deposit of microorganisms related to patent applications. Under the Treaty, which has 78 parties, there are 42 laboratory facilities that are

[2] The Fifty Third session of the WIPO Assemblies in May 2014 will take stock, consider the progress made on the text(s), and decide on convening a Diplomatic Conference.

recognized as International Depository Authorities (IDAs) for materials associated with patent applications. These IDAs are located in 23 countries.

The Budapest Treaty does not define microorganism and, in practice, is used for deposits not just of single celled organisms, but also material of higher organisms, including plant seeds and cell lines of plants and animals (including humans). The Treaty is also used for patent deposit of DNA and RNA in various forms.

A striking confidentiality is maintained surrounding Budapest Treaty deposits. On the one hand, this is intended prevent premature disclosure of an invention, but on the other it impedes identification of the origin of deposited genetic resources. IDAs are required to "*comply, in respect of the deposited microorganisms, with the requirement of secrecy*" [Article 6 (2) (vii)], which is elaborated in the Treaty's regulations (Rule 9.2) as:

> *No international depositary authority shall give information to anyone whether a microorganism has been deposited with it under the Treaty. Furthermore, it shall not give any information to anyone concerning any microorganism deposited with it under the Treaty except to an authority, natural person or legal entity which is entitled to obtain a sample of the said microorganism ...*

Thus, the mere existence of a Budapest Treaty deposit is a secret that is typically only revealed when a patent application that makes reference to that deposit is published. Generally, such applications exert patent claim over the deposit. Prior to the issuance of a patent, except to relevant patent offices, the material and information about it may not be released to anyone without the depositor's specific permission.

The Parties to the Budapest Treaty include most of Europe, North America, and developed countries in other regions, as well as most countries of the former USSR. Membership among countries of the South is considerably more limited.[3] In Africa, only Morocco, Senegal and South Africa are parties. In Latin America the Treaty has been more frequently ratified, but not by countries including Brazil, Argentina, and Colombia. Asia's largest countries, China and India, have ratified the Treaty, but many others in the region have not.

III METHODOLOGY

To identify a pool of Patent Cooperation Treaty (PCT)[4] patent applications with an associated deposit under the Budapest Treaty, a search of the WIPO Patentscope database was performed for patent applications assigned to the C12N international patent classification, applicable to inventions involving microorganisms. The search was restricted to those C12N applications that also contained the term "Budapest" in the specification (main text), as well as the word "deposit" (or "deposited") in the claims.[5] This search was conducted for the period 2010 through June 2013.

[3] Ratification of the Budapest Treaty is often sought by developed countries in the context of free trade agreements. For example, Central American countries ratified in the late 2000s due to a regional free trade agreement with the US.

[4] Both the PCT and Budapest Treaty are administered by WIPO.

[5] Patent applications with Budapest Treaty deposits typically make reference to the treaty when identifying the deposit, e.g. "Purified cultures of microbial strains described in the present disclosure were deposited in the Agricultural Research Service Culture Collection located at 1815 N. University

The searches resulted in an initial total of 199 matching patent applications. In the course of evaluation, 12 of these matches were excluded as inappropriate for this analysis,[6] resulting in a final sample of 187 applications.

This search method was not intended to identify all patent applications with a related deposit under the Budapest Treaty, nor all C12N patent applications claiming a genetic resource. It did not, for example, capture applications claiming genetic resources but not assigned to the C12N category, or those that have associated deposits but which did not match the other search terms. Searches were only conducted of patent applications published in English.

Rather, the search was designed to identify a pool of recent C12N patent applications that claim a genetic resource, in order to read and evaluate those applications to determine if the country of origin of the claimed resource is disclosed.

To assess disclosure, each patent application was read for disclosure of origin details. Because there is no requirement for disclosure under the PCT and no standardized disclosure format, disclosure of origin might occur at any place in the patent application, making the patent evaluation process laborious.

The country of origin of the patent applicant, the repository where materials were placed, and, if disclosed, the country or origin of the genetic resource were noted for each patent application.

This study focuses on disclosure in patent applications. Thus, analysis of disclosure was strictly focused on whether or not the origin of the material deposited could be discerned from the patent application. Additional sources were not consulted to attempt to determine the material's origin, nor were the patent claims systematically analyzed to determine the extent to which they cover the deposited materials[7] (although some examples of these analyses are provided later in the report).

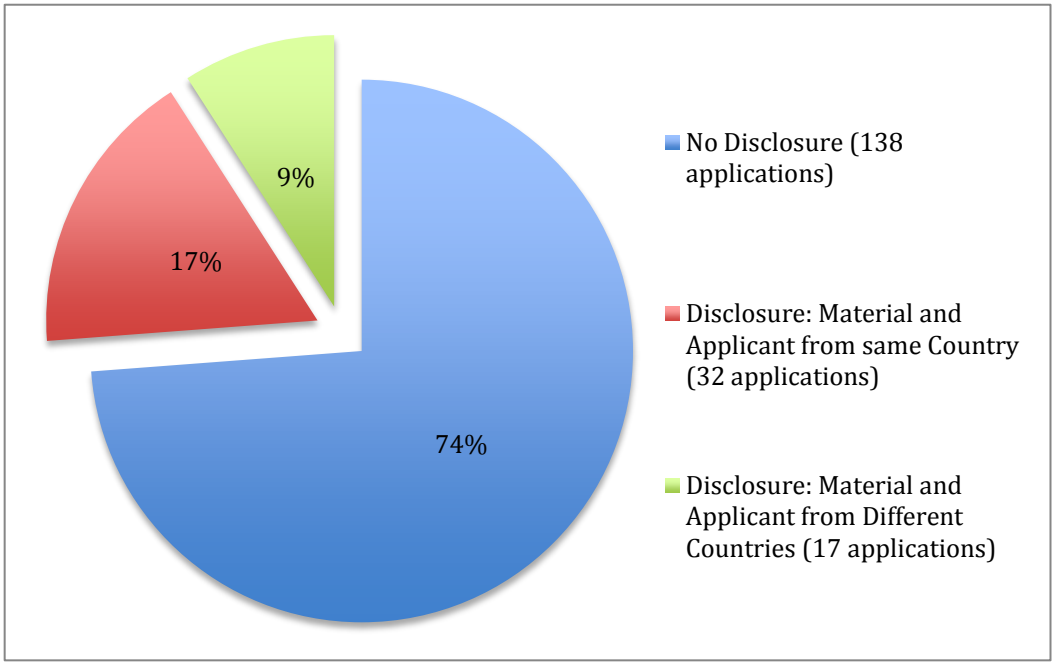
Street, Peoria, IL 61604, USA (NRRL) in accordance with the Budapest Treaty for the purpose of patent procedure and the regulations thereunder (Budapest Treaty)." (From PCT patent publication WO2013090628.)

[6] These patent applications were typically biomedical inventions involving model organisms such as laboratory animal breeds and/or commonly used animal cells, for example for the creation of hybridomas or antibodies.

[7] For example, a patent application whose direct object is a gene may involve deposit of that gene expressed in a cell line, seed, or microbe. These associated materials incorporating the gene are typically claimed in the patent application but may not be its principal subject.

IV RESULTS

Rate of disclosure of origin for C12N-classed international patent applications 2010 through June 2013 (Sample size=187)



Reading of each patent application revealed that nearly three quarters (138/187) did not disclose the country of origin of materials deposited under the Budapest Treaty. This simple statistic indicates that a disclosure requirement would change present practice because a large proportion of C12N patent applications claiming genetic resources do not reveal their source – legitimate or otherwise.

The prevalence of non-disclosure creates an obvious opportunity to avoid revealing misappropriation of resources, and also may cast doubt on legitimate claims due to a lack of information.

Another interesting observation is that almost twice as many (32/49) genetic resources claimed in patent applications whose origin was disclosed were from the same country as the patent applicant. Because cases of the claimant and resource being from the same country are less likely to raise biopiracy concerns, patent applicants may actively choose to not reveal the origin of deposited genetic resources when they are from third countries. This cannot be stated conclusively, however, because of the secrecy surrounding Budapest Treaty deposits, which makes it impossible to develop necessary data.

In some instances of non-disclosure it was possible to identify the country of origin of the deposited genetic resource through additional research. In cases where the unidentified genetic resource could be traced to a third country, this country was often in the South. (See examples, beginning on page 13.) In the full sample of 187 patent applications, no instances of South entities patenting North resources were identified.

Surprisingly, the impact of ratification of the CBD on disclosure of origin in patent applications appeared minimal, suggesting that a country's status as a CBD Party has little influence on the disclosure behavior of its companies and other patent claimants.

In the sample, patent applicants from CBD Parties were only very slightly more likely to disclose the origin of deposited genetic resources than patent applicants from the United States (the only non-Party represented in the sample). The following chart shows the very small overall effect on disclosure rates of separating US-origin patent applications, which results in only a 1% increase in the total rate of disclosure:

	Applications	*With disclosure*	*Rate of disclosure*
Full sample	187	49	26.2%
CBD Parties	114	31	27.2%
United States	73	18	24.7%
European Union	***69***	***12***	***17.4%***
EU, Switzerland, and Norway[8]	83	17	20.5%
Other Developed[9]	22	10	45.5%

The patent applicants that are CBD Parties are overwhelmingly from the North[10] and these applicants are no more likely to disclose the country of origin of deposited genetic resources than their US-based counterparts.

Notably, the poorest performing regional group for disclosure is the European Union (EU), whose 17% rate lagged significantly behind that of both the United States and CBD Parties as a whole. Adding the results of Switzerland and Norway to the EU results in a modest improvement, but one in which Europe still lags behind other regions.

On the other hand, due to the large number of patent applications from its companies, the United States alone accounted for almost 40% of all instances of non-disclosure (55/138), and disclosure of origin in patent applications by US companies disproportionately includes cases where US companies claim US genetic resources (12 of 18 disclosures), perhaps indicating a particular willingness to disclose by US companies when the resource is not from a third country and/or CBD party.

Other developed countries showed an improved result of 45% disclosure, in largest part due to Australia's significantly higher than average (71%) disclosure rate. Like the US result, however, Australia's relatively good performance is influenced by the fact that 4 out of 5 disclosures made by its patent applicants were claims on Australian resources.

[8] Excludes patent applicants from offshore investment companies that may be controlled by European interests.

[9] This category includes Australia, Canada, Israel, Singapore, New Zealand, and South Korea.

[10] Placing an exact number on this group is difficult because several patent applications are assigned to entities in Hong Kong, Barbados, and the Cayman Islands that appear to be offshore investment companies controlled by European, Canadian, or Australian directors and capital.

The following two figures track the rate of disclosure for each country either with a disclosure or with three of more patent applications in the sample.

Rate of disclosure of origin by applicant's country

Country	Total Applications	Number with Disclosure	Percent
Australia	7	5	71%
Canada	4	2	50%
Denmark	20	1	5%
France	10	1	10%
Germany	18	2	11%
India	2	2	100%
Israel	3	0	0%
Italy	5	3	60%
Netherlands	8	2	25%
New Zealand	2	1	50%
Norway	1	1	100%
Singapore	3	2	67%
Spain	1	1	100%
South Korea	3	0	0%
Switzerland	13	4	31%
United Kingdom	4	2	50%
United States	73	18	25%
Others	11	2	18%
Total	***187***	***49***	***26%***

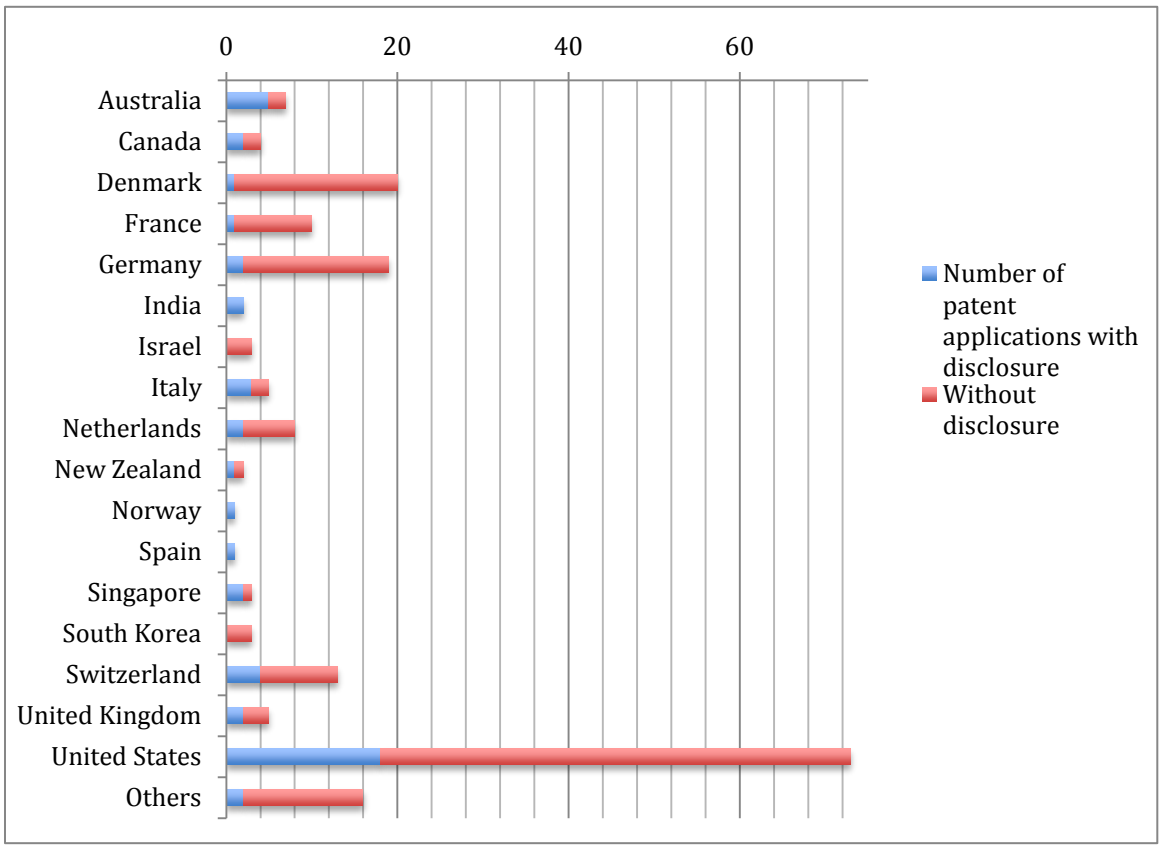
In instances where there was disclosure, the following relationships existed between the country of origin of the deposited resource and the country of the patent claimant:

Disclosures and Respective Origin of the Patent Deposit

Instances	Country of Genetic Resource Origin	Country of Applicant
4	Australia	Australia
1	Canada	Canada
1	Canada	Denmark
1	Central African Republic	USA
1	China	USA
1	Denmark	USA
1	Ecuador	Switzerland
1	France	France
2	Germany	Germany
2	India	India
1	Ireland	UK
3	Italy	Italy
2	Ivory Coast	Undetermined[11]
1	Mexico	Canada
2	Netherlands	Netherlands
1	New Zealand	New Zealand
1	Norway	Norway
1	Sierra Leone	USA
1	Singapore	Singapore
1	Spain	Spain
1	Sweden	Australia
1	Switzerland	Switzerland
1	Uganda	USA
1	UK	UK
1	USA	Singapore
1	USA	Switzerland
1	USA	Switzerland
12	USA	USA
1	Vietnam	USA

[11] World Wide Carbon Credits, with two patent applications related to algal biofuels, is a limited liability company registered in Hong Kong. Both of its directors presented Australian passports at the time of its incorporation. It is managed from New Zealand with investment from a fund created by the Cayman Islands subsidiary of a UK offshore banking firm based on the island of Jersey.

Disclosure of origin by applicant's country



Incidental Disclosure and its Effects

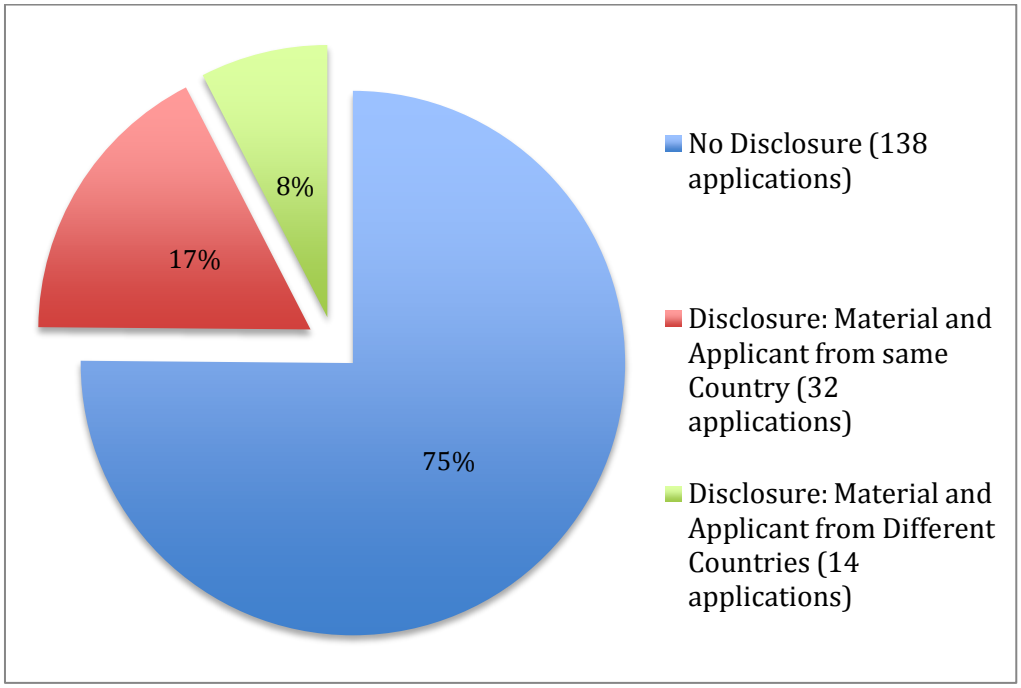
The study used a forgiving definition of disclosure – if the country of origin of a genetic resource could be discerned anywhere in the patent application, then the application was deemed to disclose the origin of the resource, without regard to the claimant's intent.

Reflecting the difficulty of disclosure assessment in the absence of a requirement and standard format, however, three patent applications that were deemed to have provided disclosure of origin only did so incidentally. In these cases, the scientific name of deposited material contains a geographic reference indicating its country of origin (one case each of materials from China, Mexico, and Vietnam), and these genetic resources appear to be endemic or near endemic. These cases were deemed disclosure. All involve genetic resources from a different country than the patent applicant, a further suggestion that cases of non-disclosure may frequently involve claims over genetic resources from third countries.

If the three cases of incidental disclosure are deleted from the sample due to ambiguity about the patent applicant's intent to disclose, then slightly over three quarters (75.1%) of the sample did not provide disclosure, and the proportion of applications divulging an origin in a third country slides to under 8% (14/184).

This, with the study's generous approach to awarding disclosure status, the nearly 75% non-disclosure rate is, if anything, an underestimate. Several other patent applicants were given the benefit of the doubt when the information contained in the application was suggestive of a specific country of origin but not entirely explicit. For instance, in patent application WO2010092155, researchers at the transnational corporation BASF reveal deposited bacterial strains isolated from a "cow of German origin". Although this statement does not unequivocally establish that the cow or the bacterial strains are German genetic resources, in this application and type of circumstance, patents applicants were given the benefit of the doubt and the application deemed to disclose, in this case, a German origin of the deposit.

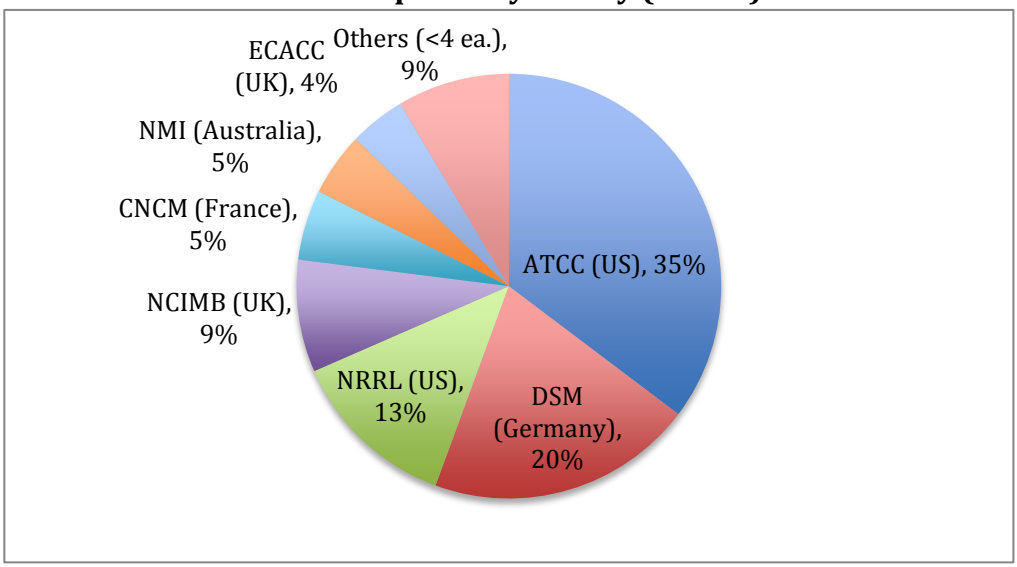
Rate of Disclosure of Origin, without incidental disclosures (n=184)



Use of Budapest Repositories

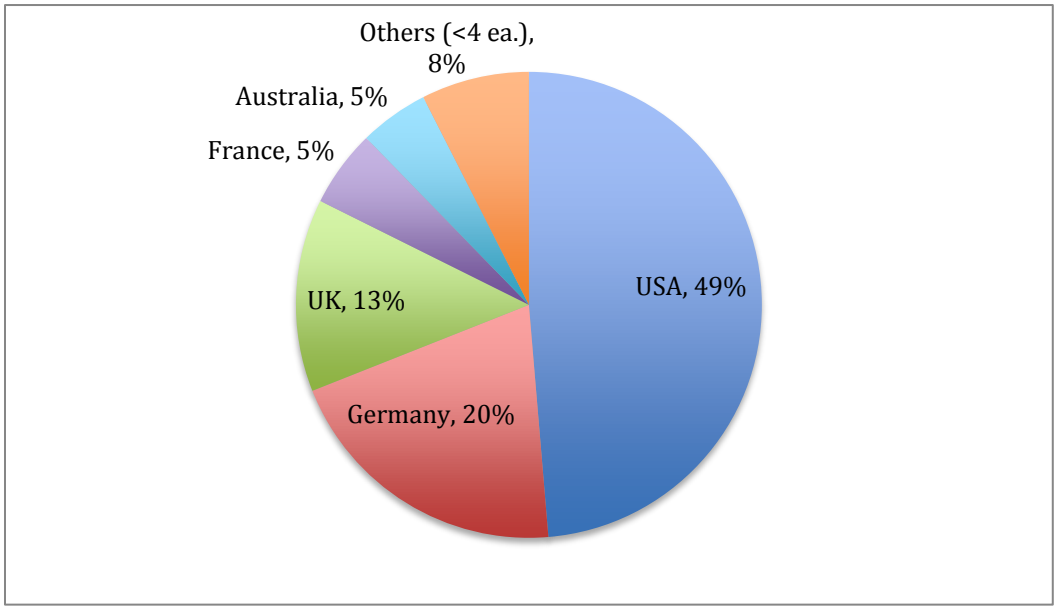
As of April 2013, there are 42 international depository authorities for the Budapest Treaty, located in 23 countries. In the study's sample of recent deposits related to patent applications in the C12N international class, however, the repositories were very unevenly used. Nearly all patent deposits in this sample were made in the US or Europe. A small number of deposits were made in Australia, South Korea, India, and Canada. A high number of deposits are made in the US and Germany.

Patent deposits by facility (n=187)



A portion of this result is likely attributable to language bias. For example, this study did not evaluate patents published in Japanese, which would likely have revealed patent deposits made at repositories in Japan. Other factors may include the efficiency of repository institutions from the depositor's standpoint, or convenience relative to the location of research activities.

Patent deposits by repository country



V EXAMPLE CASES OF NON-DISCLOSURE IN THE STUDY SAMPLE

To offer more detail on those patent applications where there was no disclosure of origin, a number of applications were selected for further research and, by consulting scientific and other relevant publications, the origin of deposited materials could sometimes be determined, even if not stated in the patent application.

In some cases the (apparent) origin is not suggestive of biopiracy. For example, US researchers working for a company cleaning up a former military nuclear site have claimed microbes that help break down toxic chemicals leaked into the environment. The researchers appear to have found the microbes in a contaminant flume at the former weapons complex itself, thus suggesting it is a US-origin genetic resource, although the patent application does not state as much, so a firm conclusion about the genetic resources' origin cannot be drawn.

Although an attempt to identify the origin of the patent deposit in all 138 patent applications without disclosure was beyond the scope of this report, a brief search led to the identification of several ambiguous cases that raise questions about possible misappropriation.

WO2013076729, a patent application submitted by Danziger Dan Flower Farm, an Israeli ornamental flower company, claims plants of the *Otomeria* genus originating in East Africa. The seeds of several such plants were deposited at the Korean Collection for Type Cultures. The company has commercialized the plants in the US, where it has large business interests and has obtained patents. The genus is not commonly sold as an ornamental plant, and Danziger's is the only commercial offering of *Otomeria*. Danziger's international patent application claims any *Otomeria* plant "characterized by red, pink or pure-white flowers." The patent application indicates the company worked with "wild type" germplasm but does not divulge where Danzinger obtained these *Otomeria* seeds.

WO2013050582, a patent application submitted by Direvo, a German biotechnology company, claims heat-loving (thermophilic) bacteria of use in producing ethanol from cellulose. The patent application claims 8 such strains deposited at DMZ in Germany, as well as relatives of them, and states that the strains were isolated from environmental samples at hot (>70 C.) locations. There are at least 15 recognized species of *Thermoanaerobacter*, some of which are linked to specific geographic origins, however, the Direvo patent application does not assign its deposits to a particular species and does not reveal where they were collected.

WO2012112411, a patent application submitted by US-based DuPont subsidiary Pioneer Hi-Bred, claims a gene promoter sequence obtained "from the elite inbred line BTX623" of sorghum, without further explanation of its origin. Although not stated in the patent application, BTX623 is a designation from Texas A&M University, which created the inbred sorghum by crossing an Ethiopian farmers' variety (SC170) and another seed called Combine kafir SA 5765-10-2, a name strongly suggesting a South African origin. The African origin of Pioneer's gene is known to specialized sorghum researchers but not stated in the patent application.

WO2012031851, a patent application submitted by Chr. Hansen, a Danish food and feed ingredient maker, claims strains of lactic acid bacteria, such as those used to make yogurt, which produce vitamin K2. These are deposited at DSM in Germany.

Where the company obtained these strains, however, is a mystery. The patent application only states that the company "*tested a large array of wild-type lactic acid bacteria strains of the species* Lactococcus lactis ..." Nothing more about the strain's origin is revealed. (Chr. Hansen has several more patent applications that similarly fail to reveal the origin of deposited genetic resources.)

WO2011068468, a patent application submitted by Best Environmental Technologies, a Barbados company that appears to be controlled by Canadian interests, claims a *Paenibacillus polymyxa* bacterium and its use as an antibiotic. It has deposited the bacterium at the ATCC in the United States. *P. polymyxa* strains are beneficial soil microbes in agriculture, where they protect plants from disease, and have been the source of human and veterinary drugs including the widely used antibiotic polymyxin. Where the company obtained this new strain is not divulged in the patent application, which merely states that it was isolated from "an animal feed additive". The company operates in Australia, Canada, Ghana, Togo, Nigeria, India, Vietnam, Mexico, and several Caribbean countries.

WO2010119114, a patent application submitted by Deinove, a self-described "cleantech" company from France, claims strains of heat loving *Deinococcus* bacteria, which it calls "high performance metabolic bacteria." It has placed them in the CNCM depository in France. The entire business strategy of Deinove is built around various uses of *Deinococcus* species, in applications ranging from perfumes to plastics and antibiotics to biofuels. *Deinococcus* isolate*s* have been obtained from Italian and Thai hot springs, Chinese and Chilean desert soils, and many other places. Where Deinove obtained the isolates claimed in this patent application is not stated. It simply says that they were "isolated from environmental samples."

CONCLUSION

This study of almost 200 recent international patent applications claiming a genetic resource finds that three quarters of patent applicants do not disclose the country of origin of genetic resources that appear in their claims and are deposited in a Budapest Treaty repository. Among the minority of patent applications in which disclosure was made, in nearly two thirds of cases the applicant and the genetic resource were from the same country. Only in less than one in ten patent applications did the applicant divulge that a genetic resource being claimed originated in a third country, suggesting that patent applicants may avoid disclosure when claiming genetic materials from elsewhere.

In the study sample, ratification of the CBD in the country of the applicant had little effect on disclosure of origin of genetic resources in patent applications. This indicates that accession to the CBD is in itself insufficient incentive to prompt corporations to reliably disclose of the origin of genetic resources that they claim. Indeed, the poorest performing regional group was the European Union, whose members have all ratified the CBD, but whose companies divulged the origin of genetic resources they claimed only 17% of the time.

The strict secrecy that surrounds deposits of biological materials made under the Budapest Treaty impairs implementation of the CBD's requirements for access and benefit sharing by hindering identification of possible misappropriation and, in this

study, development of a more detailed picture of disclosure practices in C12N-classed patent applications involving a deposit under the Treaty.

The results of this study may be used to support the goal of many developing countries that disclosure of origin of genetic resources in patent applications should be required, and indicate that international measures beyond the CBD and its Nagoya Protocol are necessary to ensure patent procedures with the capability of reliably identifying cases of possible misappropriation, so that appropriate resolution procedures can be invoked.