MICHIGAN STATE UNIVERSITY

DEPARTMENT OF MICROBIOLOGY AND MOLECULAR GENETICS
6162 BIOMEDICAL AND PHYSICAL SCIENCES BUILDING

EAST LANSING · MICHIGAN · 48824-4320
FAX (517) 507-5450

Mr. Timothy J. Hodges
351 St. Joseph Blvd.
Gatineau QC K1A 0H3
Canada
Tel ; +1 819 956 9885

10 September 2010

RE: *Monitoring and Tracking Genetic Resources*

Dear Mr. Hodges,

I am writing to you as an interested party and to lend my support to your efforts in facilitating the negotiations and resolving the text of the International Regime for Access and Benefit Sharing.

I am the lead author on the report entitled *Studies on Monitoring and Tracking Genetic Resources using Persistent Identifiers* that was commissioned by the Secretariat in 2008 (See UNEP/CBD/WG-ABS/7/INF/2) and a fellow of the American Association for the Advancement of Science and the Society for Industrial Microbiology. Since 1996, I have been a professor in the Department of Microbiology and Molecular Genetics at Michigan State University.

Some tools have recently been developed using technology described in the above-mentioned report to examine US patent grants to commercial and non-commercial research entities. I would like to share some of the findings (attached) and describe how this tool works prior to the critical discussions that will be held in the upcoming meetings in Montreal and Nagoya. To briefly summarize, there has been a steady increase in commercially oriented biological research in US universities during the last 15 years that has resulted in a significant number patent grants. A similar trend is emerging for non-US universities and is likely to continue. At the same time, US patent grants to commercial research entities in the same areas of research declined slightly. Taking into account the circumstances of the recently resumed session for WG-ABS9 in July in Montreal, it would seem to be in the interests of the international negotiating group, as well as the Co-chairs for the meeting, there be some appropriate mechanism to monitor *all* research activities.

The methods used in the analysis are derived from a proof-of-concept for such a mechanism that is already in place for use in the field of microbiological research. I am at your disposal and will be happy to discuss this matter with you at your convenience.

Yours sincerely,

George M. Garrity, Sc.D.
Professor, Microbiology & Molecular Genetics
Tele 517.214.8821
email garrity@msu.edu
http://www.mmg.msu.edu

cc Valerie Normand, Fernando Casas-Castañeda
Attachment:

Recent trends in US patent grants and issues to be considered

George M. Garrity[1,2] and Charles T. Parker[2]
[1]Michigan State University, East Lansing, MI, USA and
[2]NamesforLife, LLC, East Lansing, MI, USA

INTRODUCTION

The life sciences have changed radically since the Convention on Biological Diversity first opened for signatures in 1992. Traditional organism-based approaches to discovery and use of genetic resources have been supplanted by molecular approaches. Biodiversity prospecting is more likely to be a programmatic bioinformatics activity rather than an activity conducted by field scientists. Access to genetic resources is no longer centered on a hunt for novel species. Rather, the hunt is for novel genes and metabolic pathways that can be cloned into well-understood expression systems and readily scaled-up for industrial production. Information about contemporary research, development, and manufacturing practices needs to be addressed, especially when those genes do not need to be associated with their native host at the time of discovery. Information about the research organizations participating in all phases of the discovery and development process also needs to be considered, especially when it involves partnerships between academic and industrial organizations.

We present a high-level view of recent trends in the issuance of US patent grants to commercial and non-commercial research organizations, and introduce a technology that is already in place which can be applied to monitoring the use of genetic materials by various stakeholders in an open and transparent manner, as intended under the International Regime for Access and Benefit Sharing (ABS).

TECHNICAL BACKGROUND AND INFORMATION SOURCES

We recently used tools that were built on the technology described in the white paper, *Studies on Monitoring and Tracking Genetic Resources using Persistent Identifiers* that was commissioned by the Secretariat in 2008 (UNEP/CBD/WG-ABS/7/INF/2) to examine US patent grants to US and non-US based commercial and non-commercial research organizations in which at least one named species of *Bacteria* or *Archaea* was mentioned. The rationale for conducting this study was to establish if there is a factual basis for the assumption that non-commercial research organizations do not proactively pursue patent protection for their inventions in which genetic resources are involved.

Our study made use of a database and technology belonging to NamesforLife, LLC (East Lansing, MI, USA; http://services.namesforlife.com) that was developed to support a name resolution service for use in the life sciences. The methodology employs a novel data model and persistent identifiers to monitor and track name changes that result in cases where the same organism is known by multiple names over time. The current target group is bacteria and archaea, but the methodology is generalizable. The persistent identifiers are used to directly access various classes of information that relate to each validly named organism. Application software developed by the company scans electronic versions of published articles, documents or database records to detect biological names and either embeds the correct persistent identifier for future use or provides end-users with direct access to information about the named organism directly from the page that is displayed in a web browser (Figure 1). Current applications provide access to concise information, including history of the name, synonyms, repositories where the organism is available, key literature references and links to specific gene and genome sequences, where available. The data model is extensible and supports the inclusion of virtually any type of information that might be tied to a specific organism, and can easily include links to digital copies of PICs, MTAs, or similar documents, for users with the appropriate privileges.

The company also maintains information about the occurrence of all bacterial and archaeal names in each document processed by our tools. This “nomenclatural fingerprint” can be used to index and retrieve the documents relating to a specific organism or group of organisms, even if name changes may have oc-

curred over time. The technology also allows proactive monitoring of the scientific, technical, medical, regulatory and patent literature and harvesting of new information on any validly named organism.

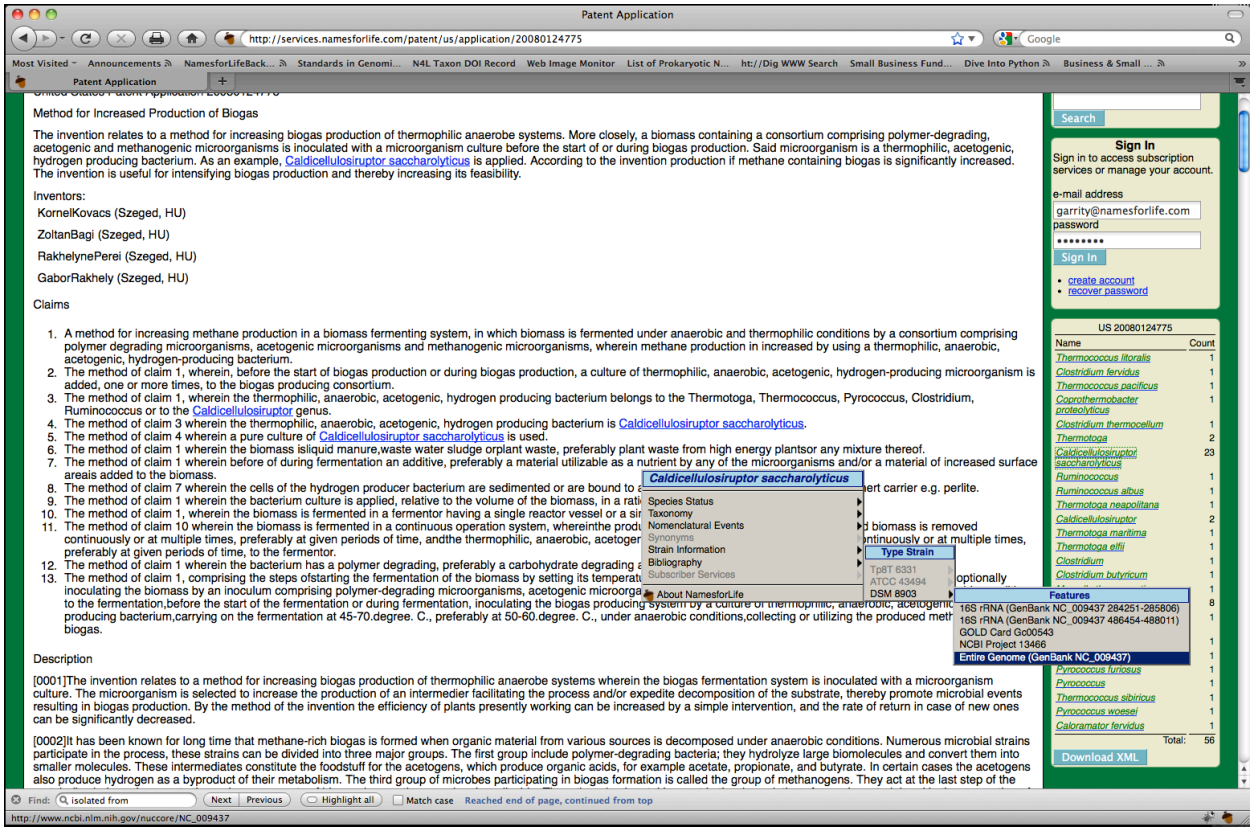

Figure 1. An example of an annotated US patent application from the NamesforLife patent database. Note linked names present in the body of the document and the N4LGuide pop-up showing detailed information for the species *Caldicellusurptor saccharolyticus*. A complete listing of all bacterial and archaeal names found in this patent application, along with frequency distribution of names is shown in the right sidebar. Source, NamesforLife, LLC.

NOTABLE FINDINGS

From January 1971[1] through July 2010, there were 92,063 patent grants making reference to one or more bacteria or archaea. As expected, US and non-US companies were awarded most of these patents (51.2 and 32.2%, respectively). What was unexpected was the finding that US academic institutions (including museums and herbaria) ranked third, with 9.2% of the patent grants. The number of patent grants to non-US academic institutions was relatively small in comparison (1.2%). What is noteworthy is the overall upward trend in patent grants issued to both US and non-US academic institutions. These have increased by four-fold since the first Conference of the Parties. During the same time, patent grants to non-US commercial entities dropped by 20% and those to US-based companies remained essentially unchanged.

In addition to the changes in technology mentioned above, academic institutions have also changed, especially in the US. Since 1980, recipients of federal funding are required to commercialize discoveries of faculty, staff and students, whenever possible. What is less obvious is that the inventions belong to the institutions, not the faculty or staff, as do all of the research funds, materials, research records and equip-

[1] The data from the USPTO available in digital form between 1971 and 1975 is incomplete. Also, our preliminary analysis of the data is based on the first assignee mentioned in each patent grant. We have not yet quantified the instances of multiple assignees. This should not affect the basic trend, but may underestimate the number of patent grants to non-commercial entities.

ment. Faculty members are also encouraged to interact with commercial entities to help increase revenues and fund their research. Faculty members also have the right to pursue research on any university-owned invention created by other faculty members, with or without the consent of the inventors. As a result, no faculty member can guarantee that their work will not be commercialized, thus the argument that there is a distinction between commercial and non-commercial research is difficult to defend, at least within the US. It is our understanding that similar policies are being pursued by institutions in the EU. Although the impact that these changes will have on Access and Benefit Sharing can only be quantified retrospectively and anecdotally, it is likely to be greater than anticipated by those who advocate special treatment for non-commercial research.

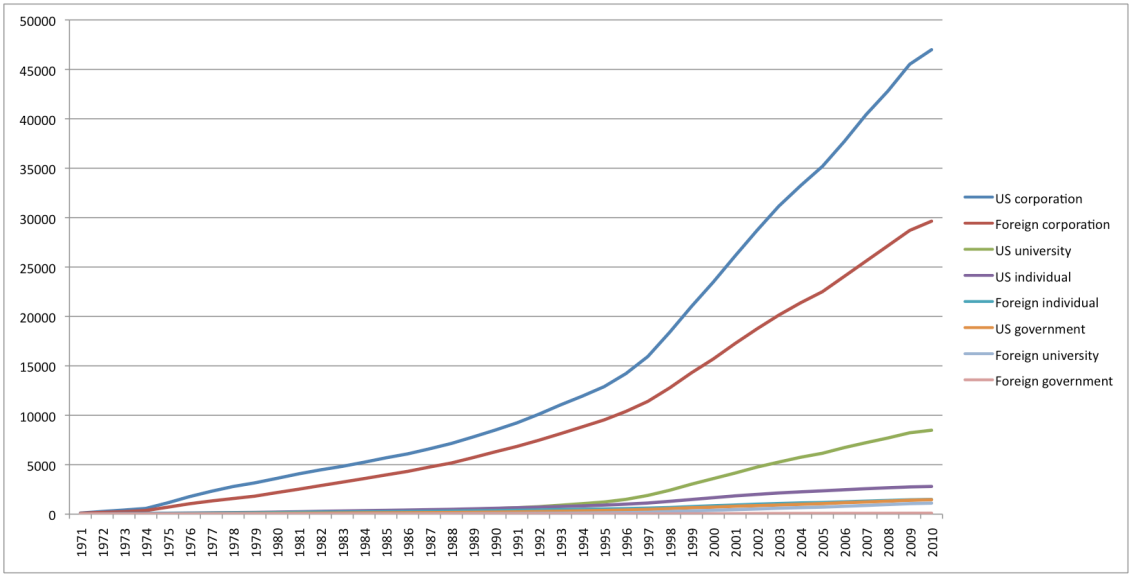

Figure 2. Cumulative number of US patent grants referencing bacteria and/or archaea to different categories of inventors Source, NamesforLife, LLC.

What is not discernable from our current analysis is the number of licensing arrangements that have occurred between academic institutions and commercial entities. Similarly, our analysis does not reveal the number of company sponsored research activities at academic institutions that may result in patentable discoveries that are assigned to the sponsor. These are generally private transactions and not recorded, especially when the private academic institutions are involved. We think that the above evidence is convincing and that the distinction between commercial and non-commercial research has become increasingly blurred. Both providers and commercial users of genetic resources have reason to be concerned if non-commercial research would be exempt from the ABS regime or treated differently.

CONCLUSION

Establishment of the International Regime for ABS will require delicately balancing the needs of both providers *and* users. This will necessitate an element of trust, but what is lacking in the current environment is a level of trust that would ordinarily exist between parties entering into a commercial agreement. In the absence of such a trusted relationship, what is required are independent methods of verification that parties to an agreement are abiding by the stated terms. Even the best intentioned research can have unexpected or unintended outcomes. If appropriate mechanisms can be put in place to monitor *all* research activity, it will uncover those events that should trigger sharing of knowledge and/or revenue, as intended by the Convention on Biological Diversity, even when those events are far removed into the future. It is entirely feasible to do this in a publicly transparent way. The key pieces are already in place.