Case Study 2.

The Kenya Wildlife Service (KWS), The International Centre for Insect Physiology and Ecology (ICIPE), and Novozymes and Diversa (Verenium) Corporation: Agreements in the Industrial Biotech Sector

Key Players

Kenya Wildlife Service

Kenya Wildlife Service (KWS) is an autonomous parastatal body supervised by a Board of Trustees with exclusive authority over national parks and significant influence over other categories of protected areas. The KWS was established under the Wildlife (Conservation and Management) Act of 1977 (and amended in 1989) (Lettington, 2003). KWS is charged with the protection and conservation of the country's biodiversity, and its mission is "to sustainably conserve and manage Kenya's wildlife and its habitat in collaboration with stakeholders for posterity". It is part of the Ministry of Tourism and Wildlife, and to date has been the ABS focal point for collections made in Kenya's 61 national parks and reserves (but not outside these areas), which include a number of Rift Valley soda lakes with microorganisms of interest to the biotech industry. KWS is also responsible for conducting and coordinating research activities in the field of wildlife and conservation management, as well as regulating research in protected areas, including vetting research proposals and issuing permits for research and for the export of any samples (KWS, 2006; Lettington, 2003). As such, they have directly entered into a number of agreements with outside partners, including Novozymes and Diversa. Other commercial partnerships are less public, including one for crop protection and another focused on insect venoms.

The International Centre for Insect Physiology and Ecology (ICIPE)

ICIPE was established in Kenya in 1970 to "help alleviate poverty, ensure food security, and improve overall health of peoples of the tropics by developing and extending management tools and strategies for harmful and useful anthropods, while preserving the natural resource base through research and capacity building." ICIPE has 233 regular staff members, drawn mainly from the developing world, and of these 45 professionals. Most staff are based at the headquarters in Nairobi (www.icipe.org). ICIPE partners with KWS for bioprospecting contracts, and this relationship is detailed in the "Memorandum of Agreement for Partnership in Discovery and Development of Products Identified from Kenyan Arthropods, Microorganisms, and Plants". For academic agreements involving the transfer of material, ICIPE drafted in 2000 an "Agreement for the Transfer of Biological Material and/or Related Information" (www.wipo.int/tk/en/databases/summaries/icipe.html). ICIPE is also involved in commercial partnerships associated with its work on insects, including that with the venture capital company Bridgeworks, based in Switzerland. Bridgeworks Africa involves a partnership with ICIPE to develop botanicals, biopesticides and fertilizers, microbial pest control, and insect attractants, repellents and traps. The agreement affords Bridgeworks a "right of first refusal" on all new

developments coming out of the research partnership, with benefit-sharing including royalties and technology transfer (www.bridgeworks.ch).

Novozymes

Novozymes is a biotech company based in Denmark, primarily owned by Novo A/S, a wholly-owned subsidiary of the Novo Nordisk Foundation. The company focuses on products that improve industrial performance and quality while saving water, energy, raw materials, and waste. Novozymes has around 4,500 employees, 15% of whom work in R&D, and over 700 products used in more than 40 different industries, and sold in 130 countries (www.novozymes.com). Novozymes' annual sales in 2006 were DKK 6,802 million, with an operating profit of DKK 1,340 million, and net profit of DKK 911 million. The company makes a commitment to support the International Chamber of Commerce's Charter for Sustainable Development, the Convention on Biological Diversity, the UN Universal Declaration of Human Rights, and the UN Global Compact (www.novozymes.com).

Novozymes spends 11-13% of sales on R&D focused on microbiology, biotechnology and gene technology. Their "core competencies" are genetic and biochemical diversity (culture collection, strain screening, genome sequencing, expression cloning); protein design; protein chemistry; pathway engineering; strain development and improvement; and large-scale production. They find, develop or refine enzymes and microorganisms into commercial products, and through 'state-of'the'art' biological production, produce them in large quantities for sale. Microorganisms are responsible for much of the building up and breaking down of different kinds of organic material in the environment, and Novozymes makes use of these capabilities for commercial products that clean surfaces and wastewater or improve the growth of plants. Microorganisms such as bacteria and fungi are also efficient and safe producers of enzymes that Novozymes sells for industrial applications (www.novozymes.com).

The company launches 5-8 new products a year, with development cycles for industrial or technical products – such as enzymes for biofuels and detergents – taking no more than 1-2 years from when a lead enzyme is identified, and for feed and feed products taking roughly 2-3 years, given the more involved approval procedures and requirements for toxicology (Ole Kirk, Novozymes, pers comm., 2007).

Novozymes has 2-3 partnerships with overseas research institutions running at any one time, including one previously with BIOTEC, Thailand for the collection of insect pathogenic fungi (Lange, 2004), and currently that with Kenya Wildlife Service and another in Portugal (Ole Kirk, pers comm., 2007).

Diversa (Verenium Corporation)

Verenium Corporation develops biofuels derived from low-cost abundant biomass and specialty enzyme products. Verenium, a publicly-traded company based in the US, was formed in 2007 through the merger of Diversa Corporation, which worked in enzyme technology, and Celunol Corporation, a developer of cellulosic ethanol process technologies and projects. The combination produced a company with "integrated end-to-end capabilities to make cellulosic biofuels a commercial reality" (www.verenium.com). Diversa signed an agreement with KWS and ICIPE in 2001, as

part of collections to feed its research on enzymes that can be used in industrial processing. Examples of products in this area include Luminase PB-100 and Luminase PB-200, enzymes that enhance the process of pulp bleaching in the paper making industry while reducing the use of harsh bleaching chemicals (www.verenium.com). Luminase was developed from a microbe found in a thermal feature in Kamchatka as part of a partnership between Diversa and the Center for Ecological Research and BioResources Development (CERBRD) in Russia. Enzymes are also used in products to convert plant material into cellulosic ethanol for fuel, and in animal care, including to improve the nutritional value of feed (www.verenium.com). Diversa focuses on enzymes found in microorganisms, since they are the world's most genetically diverse organisms, with broader and more varied characteristics than those observed in plants or animals. In 2005, Diversa had 18 partnerships with groups in 10 countries across six continents, and was collecting in all international waters around the world (Mathur et al, 2004; Diversa, 2005). But the 2007 merger of Diversa and Celunol into Verenium followed a restructuring at Diversa in 2006 that was intended to improve its product sales and to "conserve its dwindling cash pile" by reducing basic research, including bioprospecting partnerships (Sheridan, 2006).

The Kenya Wildlife Service – Novozymes Partnership

Background

In May 2007, The Kenya Wildlife Service and Novozymes entered into a five year partnership for the collection, identification, and characterization of microorganisms from Kenya's national parks. The current agreement grew out of pre-CBD collections that Novozymes received, and their subsequent efforts to address the absence of an agreement associated with these collections after they led to the development of a commercial product, Pulpzyme. Pulpzyme reduces the amount of chlorine needed to bleach wood pulp (Odhiambo, 2007). It remains unclear who collected the samples, or where, and they may have been the result of a staff person collecting while on holiday, a practice common in the years prior to the CBD. Within the company's database, however, the country of origin – Kenya - was clear. It was assumed that collections took place in a protected area, and thus under the management of KWS, so the company approached KWS to reach an agreement.

Commercial sales of Pulpzyme have been modest, but Novozymes sought to develop a benefit-sharing agreement for proceeds from this product in order to "make things straight… in the spirit of the CBD" (Ole Kirk, Novozymes, pers comm., 2007). A deal was negotiated to pay an accumulated royalty on past sales (the exact amount is not available), and running royalties on any future sales, as well as to build a new partnership around microorganism collection, identification, and characterization. Novozymes will train Kenyan students in taxonomy, isolation and identification of microorganisms, and will transfer advanced technology to Kenya, including knowledge of how to collect and isolate micro-organisms and how to characterize microbial diversity. The new agreement also grants Novozymes "rights on similar terms to commercially make use of specific strains isolated in Kenya which are already in Novozymes' possession." (Novozymes/KWS press release, 2007).

The partnership between Novozymes and KWS will run for five years as of 2007. Novozymes has found that with similar agreements in other countries, five years is a

reasonable amount of time to allow for training and technology transfer to provider country institutions, and for Novozymes to fully evaluate the potential of the project, and the available biodiversity (Ole Kirk, pers. comm., 2007).

The 2007 Novozymes-KWS agreement did not result from a particular interest in bioprospecting partnerships in the region on the part of Novozymes, and instead resulted from commercialization of much earlier collections, and a desire to negotiate a benefit-sharing agreement. However, the microbial diversity available in Kenya is of interest to the company, which stands to benefits from access to novel genetic resources. It is the case, however, that the company is not as dependent upon collections from nature as it was even 10 years ago. Advances in science and technology, in particular genomic science, have made it possible to access the enormous biodiversity in Denmark alone, and most of their products derive from Danish biodiversity. The company also has access to increasing numbers of genomes placed in the public domain (on average, one new microbial genome is published a week), and they are able to generate 'artificial evolution" and "diversity" in the laboratory (Ole Kirk, pers. comm., 2007).

Prior informed consent

Under the Wildlife and Conservation Management Act of 1972 (amended in 1989), KWS has jurisdiction over the management of Kenya's 61 national parks and reserves, which form the core of the conservation system. KWS is responsible for regulating research in these areas, including vetting research proposals and issuing permits for research and for the export of any samples (KWS, 2006). National parks are central government property, and reserves are the property of communities, but KWS manages research in the latter areas, as well. Additional prior informed consent from local councils or communities for collections undertaken in reserves is not required.

While KWS serves as the national focal point for ABS in national parks and protected areas, these responsibilities, and their relationship to those of the National Environmental Management Authority (NEMA) of the Ministry of Environment and Natural Resources, have been unclear since new ABS regulations were propagated in December 2006. Prior to these new regulations - Legal Notice 160 "The Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit-Sharing) Regulations, 2006", under the Environmental Management and Coordination Act (No 8 of 1999) - there was no specific ABS regulatory regime in Kenya, although elements of a potential ABS regulatory structure were in place, and a range of statutory, regulatory and policy provisions affected access and benefit sharing (Lettington, 2003). In the new regulations section 53 directly addresses access to genetic resources. NEMA is identified as the national ABS focal point, but the relationship between this new role for NEMA, and KWS' existing authority, remains unclear. Discussions are ongoing to address confusion about respective mandates and jurisdictions. At the same time, and typical to the establishment of national focal points around the world, NEMA is a new institution within government with a broad mandate and limited resources, so ABS must compete (often unsuccessfully) with other priorities (Lettington, 2003).

In the meantime, KWS continues to operate according to previous arrangements in which it grants access and receives benefits from ABS partnerships undertaken in protected areas. KWS undertakes to ensure that all necessary permits and

authorizations are obtained for partner companies (Lettington, 2003). In the absence of clear ABS measures, procedures, and institutional authorities, many companies are reluctant to engage in ABS partnerships, however the KWS role as broker and facilitator appears to provide the certainty companies need. In the case of the Novozymes partnership, KWS facilitated all permits and signed the agreement with Novozymes. Directly partnering with companies in this way is somewhat unique for park managers, although one that has been widely proposed as a way of funding expensive and critical research and management activities in conserved areas.

Access to resources

KWS will undertake all collections, and these will be in Kenyan national parks and reserves. The collections do not involve traditional knowledge. Biotechnology research programs like these do not incorporate traditional knowledge into their collecting programs due to the emphasis on microorganisms, and because their research approaches and technologies do not lend themselves to incorporation of this type of information (Lange, 2004; Mathur, 2004). The numbers of samples to be collected per year are not specified in the agreement, and the intention is that this will evolve alongside the partnership in the coming years. In the microbial discovery laboratory set up by Novozymes, and staffed by KWS researchers trained by Novozymes, KWS will undertake isolation and characterization of microorganisms. They will supply research results to Novozymes, which will then decide whether to pursue a lead or not.

Benefit-sharing

Monetary benefits
Under the agreement, KWS – as a representative of the government – will receive running royalties on any commercial product developed. The rate is confidential (see discussion below in section on the Diversa partnership). Novozymes also provides KWS with an upfront payment, a 'lump sum' that covers the costs of sample collections and laboratory work. If research results from the microbial discovery laboratory in Kenya show promise, and Novozymes wishes to pursue something further, it will request samples for research within the company's laboratories, and this will trigger a milestone payment to KWS.

Non-monetary benefits – technology transfer and capacity-building
As part of the benefit-sharing arrangement associated with Pulpzyme, Novozymes sought to expand benefits beyond the purely financial, and develop a broader collaborative project. As elaborated in the 2007 agreement, this includes establishment of a microbial discovery laboratory at KWS, with advanced technology to isolate and characterize microorganisms within Kenya. Necessary materials for implementing enzyme screening in Kenya will also be supplied (Novozymes/KWS, 2007). Staff of KWS will travel to Novozymes, with costs born by Novozymes, to be trained in these techniques, and Kenyan students will be trained in taxonomy, isolation, and identification of microorganisms. The laboratory can be used for other partnerships, as well – Novozymes does not have exclusive rights to its use.

Benefits for biodiversity conservation
Financial benefits will accrue to KWS, whose mission is "to sustainably conserve and manage Kenya's wildlife and its habitat". They will support the wide range of conservation programs undertaken by KWS, and as a result – unlike most

bioprospecting agreements – financial benefits will directly support conservation work in the region. The collections will also generate information and understanding about biodiversity critical to management and conservation in the region.

Benefits for scientific and technological capacity
By building a laboratory at KWS to undertake identification and characterization, and training researchers, a higher level of scientific research will take place than those associated with bioprospecting agreements that involve only the supply of samples. The laboratory is also available for other research projects – academic and commercial – allowing KWS to build upon the capacity resulting from this partnership. As KWS Director Julius Kipng'etich reported, in reference to this partnership: "Tourism is low level income generation. We need to graduate to a higher level where biotechnology takes us" (Odhiambo, 2007).

Intellectual property rights

Any intellectual property that comes out of the partnership will be co-owned by both parties. Both KWS and Novozymes will be listed on patents. Novozymes has a very active patenting policy, with an extensive portfolio of more than 4,200 active patents, patent applications, and licensed patents (www.novozymes.com).

Tracking and monitoring of samples

Given the structure of this agreement, with Novozymes not receiving samples, but data instead, and the request for samples for further study in Denmark triggering milestone payments, there are fewer concerns associated with tracking samples within the company program, and monitoring and compliance, than in many cases. However, Novozymes does have a very well-established tracking system in place. In general, however, developments in science and technology, and dramatic changes in the ways genetic resources are studied and used, mean that tracking and monitoring the use of genetic resources has become increasingly difficult. As a result, trust and regular communication associated with solid partnerships are important elements of tracking and monitoring, and compliance with agreements.

Agreements employed

The agreement used as the basis for discussion between Novozymes and KWS, and adopted with fairly minor changes, was one proposed by KWS. A single agreement guides this partnership, with KWS acquiring permits directly from the government on behalf of the partnership.

The Kenya Wildlife Service- The International Centre for Insect Physiology and Ecology (ICIPE) and Diversa (Verenium) Corporation Partnership

Background

In 2001, the Diversa Corporation signed a three-year agreement with the KWS and ICIPE. This was during a time of expansion in Diversa's collecting partnerships around the world, with a total of 18 partnerships by 2005 (Mathur et al, 2004; Laird

and Wynberg, 2005). In 2004, the agreement was renewed, and at that time, small changes were made in the agreement, including an increase in the flat amount payable annually for the supply of samples, and a simplification of the royalty structure in order to make it easier to manage.

KWS and ICIPE work together in this case, under the 2000 "Memorandum of Agreement for Partnership in Discovery and Development of Products Identified from Kenyan Arthropods, Microorganisms and Plants". The agreement signed with Diversa is with both KWS and ICIPE, with ICIPE managing the partnership, undertaking communication with Diversa, and receiving and then distributing to KWS its share of any financial benefits.

Prior Informed Consent

Prior Informed Consent was facilitated by KWS and ICIPE. Because collections are undertaken only in protected areas, KWS serves as the ABS focal point for the research, as described above in the case of Novozymes.

Access to Resources

KWS undertakes all field collections of material on behalf of Diversa, which provides guidance for collections, formalized in their agreement, as follows:
" Collaborators will be responsible for the collection, processing and shipment to Diversa of environmental samples from diverse habitats within the Republic of Kenya and/or DNA samples isolated from such environmental samples using the Technology. Collaborators shall further be responsible for planning and execution of collection trips with and without the participation of Diversa personnel. Collaborators will provide laboratory space for the collaboration activities. Environmental samples shall include, but not be limited to, soils, sediments, mire, earth, microbial mats and filaments, plants, ecto and endo symbiont microbial communities, endophytes, fungi, animal and/or insect endosymbionts, marine and terrestrial invertebrates, air and water. Collaborators will provide Diversa a minimum of 50 and up to 250 environmental samples per year. All such environmental samples shall be considered "Material" under this Agreement" (Appendix A, Materials, Biodiversity Collaboration Agreement).

Benefit-sharing

All KWS-ICIPE agreements with the private sector include annual fees, royalties, and technical cooperation and training, and most also include some form of milestones (Peter Munyi, ICIPE and Robert Lettington, GRPI, pers comm., 2007).

<u>Monetary benefits</u>
An annual payment is made to ICIPE/KWS from Diversa in order to cover personnel, equipment, and other costs associated with the collections. There is also a bonus mechanism built into the partnership, in which the local institutions receive a small bonus, as a percentage of base funding, if seven criteria are met: completion of data sheets; DNA from samples is supplied when requested; DNA is isolated; shipping protocols are followed; specific sample collection or re-collection are fulfilled; maximum coverage of biotypes and habitats is achieved; and the partners respond in a timely and professional manner.

Dependent upon a successful commercial product, milestone payments and royalties will be paid. As with the Novozymes case, and standard to commercial partnerships, the royalty rate for the Diversa case is not publicly available. However, on a general basis, "the range of royalties currently active for KWS-ICIPE partnerships is between 0.5% - 10%, with the lower end tending to involve highly specialized technologies that require significant value adding outside Kenya. The highest tend to involve less direct values, such as know how and other forms of licensing etc to third parties, although this obviously only involves specific technologies and not material or broader rights. The mid range of royalties tends to involve the use of material in applying more established technologies and where more of the science can be done in Kenya before delivering material. Associated with this, some agreements have incentives where there can be bonuses of up to 5% of the base annual access fees for meeting key recipient requirements for the standards of material delivered." (Peter Munyi, ICIPE and Robert Lettington, GRPI, pers comm., 2007).

Of the monetary benefits received as part of these agreements, KWS and ICIPE divide them 50/50; Diversa will pay ICIPE, which will then forward to KWS its share of the amount received. In other cases in which protected area managers are parties to agreements, such as that with Yellowstone National Park in the US or government research institutions, such as the Queensland Museum and Herbarium in their partnership with Griffith University and Astra Zeneca, financial benefits do not accrue directly to the park managers or research institutions, and will often go to state or federal government coffers.

Non-monetary benefits

License to products and inventions
KWS and ICIPE retain the right to a royalty free license to any products or inventions developed from Materials provided under the partnership, in order to allow them to research, develop and otherwise make use of any products or inventions developed from the Material within the jurisdiction of the Republic of Kenya (but not beyond this jurisdiction). This is not understood to "confer any commercial rights, or rights to transfer any products, inventions or commercial rights to third parties" (12., Agreement Terms, Biodiversity Collaboration Agreement).

Training
Under the agreement, KWS and ICIPE will receive training in technology relevant to the partnership, primarily at Diversa, and undertaken at Diversa's cost.

Research results
Under the agreement, KWS and ICIPE have the right to complete information developed by Diversa, and to research results on any novel genes or organisms discovered therefrom.

Publications
Diversa, KWS and ICIPE researchers will jointly publish the results of any research work when there is a substantive contribution by both parties, and after all parties have provided written approval. The submission and subsequent publication, however, will be delayed until any intellectual property or confidential information contained in the proposed publication is adequately protected as mutually agreed by all Parties (8., Agreement Terms, Biodiversity Collaboration Agreement).

Benefits for biodiversity conservation
In addition to the potential financial benefits that will go to KWS, and the increased biodiversity information and understanding resulting from the project, Diversa suggested that "it might consider providing matching funds for biodiversity conservation activities relating to its fields of interest' (Lettington, 2003).

Intellectual Property Rights

Under the agreement, the company retains intellectual property rights over any products that it develops, provided that ICIPE and KWS have the option of a royalty free license for local adaptation in Kenya when, and if, this is feasible (Lettington, 2003).

There were discussions within KWS and ICIPE at the time of the first agreement, and it was decided to not pursue intellectual property rights, which in any case it might be difficult for ICIPE and KWS to utilize effectively, and rather to focus on seeking greater monetary and non-monetary benefits as part of the partnership (Robert Lettington, pers. comm., 2007). The text in the Biodiversity Collaboration Agreement relating to IPRs is as follows: in the Preamble, "Whereas, Collaborators agree that Diversa will own any invention made by Diversa using the Material; and…" and in the Agreement Terms, 11. "Diversa agrees and understands that if Diversa's use of the Material results in identification of new genes, or any invention, improvement, useful composition, structural modification or derivative of the Material (any of which shall be considered a "Diversa Invention"), Diversa shall promptly disclose any such Diversa Invention to Collaborators. Collaborators agree that, subject to the provisions of this Agreement, Diversa shall own all right, title and interest in and to any or all Diversa Inventions."

Tracking and monitoring

In the agreement, Diversa agrees to assign unique identification numbers to Material sent by Collaborators, and to assure that its identification system allows Collaborators and Diversa to identify all Material and research results (Agreement Terms, Biodiversity Collaboration Agreement, 10.).

Conclusion

The partnerships formed between KWS and ICIPE, and the industrial biotech companies Novozymes and Diversa, provide a range of short, medium and long term benefits. They are also based on procedures for prior informed consent that conform to government standards for collections in protected areas, although these procedures may be in flux alongside the ABS legal framework. These partnerships build scientific and technological capacity, as well as providing support for biodiversity conservation. The scale of investment in laboratories, training, and collections is significant, if far smaller in size and scope than those that might result from pharmaceutical industry partnerships (eg see the Griffith University and Astra Zeneca partnership in Queensland).

However, these partnerships are not necessarily indicative of standard practice in the industrial biotech sector, nor of bioprospecting activities within Kenya. The details of these partnerships are uniquely public, and staff of both Novozymes and Diversa

have spent a great deal of time engaging with the CBD policy process and entering into similar partnerships around the world. Both KWS and ICIPE have a number of other commercial partnerships, the terms of which are less well known, and which may or may not live up to current standards of 'best practice' – although given the institutional capacity of KWS and ICIPE in this area, and the model contracts and agreements from which they work, it is likely that they follow these standards.

At the same time, however, a great deal of bioprospecting is underway in the country, both within and outside of protected areas, that appears to be difficult to monitor and control, and that operates without clear PIC, and sharing of benefits. The KWS-Novozymes and KWS/ICIPE-Diversa partnerships grew up at the same time concerns were raised about the use of an enzyme from a saline lake in Kenya by the US company Genencor International (eg Ngare, 2006; Mbaria, 2004; Lacey, 2006; McGowan, 2006). In 2002, the company announced the development of a product that causes a faded look in denim, and might replace the pumice stones usually employed by the industry. Genencor acknowledges that the enzyme was obtained in Kenya, but there is little detail available on the legal basis for their obtaining the enzyme. All of Kenya's saline lakes fall within the boundaries of protected areas, which means collections might have been undertaken with a KWS research permit (Lettington, 2003). Genencor says that it obtained the sample from a Netherlands-based company that took part in an academic research project with Leicester University in the UK, and that all necessary research permits were obtained (Lacey, 2006). This case remains unresolved, but has heightened awareness within the country about the need for effective ABS measures as an important complement to ABS arrangements between parties.

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