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BIOSCIENCE AT A CROSSROADS: INDUSTRIAL BIOTECHNOLOGY AND THE NAGOYA PROTOCOL*

INTRODUCTION

Industrial biotechnology has come of age in the last five years. Advances in science and technology, combined with concerns over climate change, energy security, and an interest in more efficient, cost-effective and green manufacturing processes and products, have led to rapid growth in this sector. Small and large companies, in a wide range of industries, are forming partnerships to produce biofuels, biobased chemicals, bioplastics, and a variety of consumer products like snack foods, sneakers, cosmetics, jeans, cars, medicines, vitamins, and electronics.

Industrial biotechnology companies are interested in new enzymes and metabolites from microorganisms, in particular those that can withstand industrial manufacturing conditions like extremes of temperature, pH, and pressure. A few companies prospect in areas with high species diversity, unique ecological niches and extreme environments, but most acquire materials through existing collections or from their own backyards. A significant development in this, and all sectors, is the publication of thousands of microbial genetic sequences, and the ability of researchers to transfer genetic material digitally.

WHAT IS INDUSTRIAL BIOTECHNOLOGY?

- Industrial biotechnology is the application of biotechnology to the eco-efficient production and processing of chemicals, materials, and bio-energy. It utilizes the extraordinary capabilities of micro-organisms and enzymes, their diversity, efficiency and specificity, to make products in sectors such as chemicals, food and feed, pulp and paper, textiles, automotive, electronics, and, crucially, energy.
- Industrial biotechnology is employed in a wide range of industries, including chemicals, plastics, food and feed, detergents, pulp and paper, electronics, automotive, textiles, bioprocessing catalysts, and biofuels.

GLOBAL MARKETS

- Global revenues for goods produced using industrial biotechnology in 2010 were estimated at between $65-78 billion annually, including biofuels.
- In 2010, the ethanol and biodiesel industries reached a combined wholesale value of $56.4 billion, and this is predicted to grow to $112.8 billion by 2020.
- The global market for industrial enzymes was $3.3 billion in 2010; with 6.6% growth rates, 2015 revenues of $4.4 billion are anticipated.
- The largest industrial biotech sectors are in the US, Europe, and Asia.
- Government incentives and support for industrial biotechnology around the world have played a large role in its recent expansion, particularly in the area of biofuels.
- The world's largest energy, chemical, food, pharmaceutical and other companies have recently come to embrace industrial biotechnology, resulting in a surge of partnerships with smaller industrial biotechnology (or synthetic biology) companies.

RESEARCH AND DEVELOPMENT (R&D)

- Small- and medium-sized companies were hit particularly hard by the economic crisis; as venture capital dried up, many struggled to reduce cash burn rates by cutting back on R&D.
- In addition to the private sector, government research and academic institutions, undertake biotech R&D. These

* For more information on this sector, and references, see the Bioscience at a Crossroads policy brief on the industrial biotechnology industry by Sarah A. Laird, at www.cbd.int/abs.

UNEP CBD gef People and Plants international UNITED NATIONS UNIVERSITY UNU-IAS Institute of Advanced Studies

groups then partner with the private sector to commercialize research results and new technologies.

- However, industrial biotech R&D weathered the storm of the economic crisis better than other areas of biotech. It is significantly less costly and less risky than biopharmaceutical R&D, and recent advances in science and technology, government mandates and incentives, and the growing interest of larger companies helped fuel a new wave of research and commercial interest.

ADVANCES IN SCIENCE AND TECHNOLOGY

- The last decade has seen dramatic advances in researchers' ability to access the genes that encode enzymes responsible for the biosynthesis of secondary metabolites. "Genome-mining", or metagenomics, allows researchers to search directly within a soil or water sample for genes without having to culture the organism.
- Sequencing of whole genomes has become 'commonplace, rapid, and relatively inexpensive', with thousands of whole bacterial genomes in the public literature.
- Genetic material can now be transferred digitally; it is now possible to collect material in one country, and send it via the internet to a laboratory in another, in a matter of days.

DEMAND FOR ACCESS TO GENETIC RESOURCES

- Industrial biotechnology companies are interested in novel enzymes found in microorganisms, but most access material through internal or external collections; only a few undertake collections outside their country, and the use of traditional knowledge is limited or non-existent.
- Some companies seek out genetic diversity by collecting in areas with high species diversity, extreme environments, or unique ecological niches.
- Microorganisms called extremophiles are of particular interest to researchers today. Found in extreme environments like hydrothermal vents, deserts, caves, cold seeps in the deep sea, salt lakes, and subglacial environments in Antarctica, these organisms live in environments similar to those required by industrial processes.

THE NAGOYA PROTOCOL: RESPONDING TO SCIENTIFIC, TECHNOLOGICAL, POLICY AND MARKET CHANGE

Although much of the industrial biotechnology industry is largely unaware of the Convention on Biological Diversity and the Nagoya Protocol, those companies with awareness of the CBD have voiced concerns similar to those in other sectors: a need for clarity and streamlined procedures for accessing genetic resources, ideally coordinated across regions, and a need for government departments in charge of ABS to better understand the scientific, technological and business realities of their sector. The Nagoya Protocol responds to these and other concerns as follows:

Helping researchers and companies follow ABS laws – In addition to supporting information-sharing mechanisms and tools at the international level like the ABS Clearing-House (Article 14), the Nagoya Protocol encourages governments to establish information dissemination and outreach programs, and to help researchers identify and follow what will be streamlined ABS procedures.

Legal certainty and clear, workable regulations – Difficult, time-consuming and bureaucratic regulations and permitting procedures, and an absence of legal certainty when acquiring genetic resources from some countries is of concern to some industrial biotech companies seeking access. The Nagoya Protocol requires Parties to designate a national focal point on ABS to make information available on procedures for obtaining prior informed consent and reaching mutually agreed terms and one or more competent national authorities to grant access (Article 13).

Building the capacity of governments – Article 22 of the Protocol also calls for building capacity to effectively implement the Protocol, including the development and implementation of ABS legislation, negotiation of mutually agreed terms, and improved research capacity to undertake research on their genetic resources. Article 21 also provides that Parties are to take measures to raise awareness of the importance of genetic resources, traditional knowledge associated with genetic resources and related ABS issues.

Defining the scope and activities covered by ABS measures – The Protocol applies to genetic resources within the scope of Article 15 of the CBD (Article 3). In addition, as further clarified by the Protocol (Article 2(c)), ""utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention". Governments may also wish to consider, when developing ABS agreements and national ABS measures, particularly in relation to monitoring the utilization of genetic resources, that information on genetic resources is often transferred digitally.

Responding to scientific and technological advances – The process through which the Nagoya Protocol is implemented provides governments with an opportunity to update and modify previous ABS strategies in order to accommodate dramatic new scientific, technological and business realities. Awareness and understanding of the industrial biotech industry is particularly low, and existing legal and policy frameworks that impact this sector and overlap with ABS are often patchwork, and have not kept pace with recent rapid advances.

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