



BIOSCIENCE AT A CROSSROADS: THE PHARMACEUTICAL INDUSTRY AND THE NAGOYA PROTOCOL*

The global pharmaceutical industry is in a time of transition, with market growth in Europe, the US and Japan slowing while emerging markets boom. Patents on many of the most profitable drugs are expiring, leading to a decline in revenues, but there are fewer new drug candidates in the pipeline. Most natural product drug discovery is undertaken today by smaller companies, government, and academia, and promising products are then licensed to larger companies for development. The demand for access to genetic resources is thus generally from smaller groups, rather than from large companies.

Demand for access to genetic resources has changed significantly in recent years as a result of rapid and on-going scientific and technological advances. These advances have transformed our understanding of the natural world and our ability to study it. Earlier difficulties associated with screening natural product samples, isolating active compounds, and scaling up raw material supply are falling away, and natural products research is quicker, cheaper, and easier than even five years ago. The material that researchers and companies access has also changed, with the vast majority of research now done on microorganisms, including those found in the sea. In all cases, it is the genetic material found within organisms, rather than the organisms themselves, that is of greatest interest to researchers.

The timing of the Nagoya Protocol to adapt to these new realities, and incorporate lessons learned from the last 20 years of access and benefit-sharing policy implementation under the Convention on Biological Diversity (CBD), could not be better.

* For more information on this sector, and references, see the *Bioscience at a Crossroads* policy brief on the pharmaceutical industry by Sarah A. Laird, at <https://www.cbd.int/abs/policy-brief/default.shtml/>.

GLOBAL MARKETS

- ▶ The global pharmaceutical industry had estimated revenues of \$955.5 billion in 2011, with the North American market the world's largest at 41.8%, followed by Europe at 26.8%.
- ▶ Growth in the largest pharmaceutical markets – the US, Europe, and Japan – has slowed significantly in recent years but there is rapid growth in emerging economies such as Brazil, China and India.
- ▶ When all factors are considered, global spending on medicines will continue to rise, and is estimated to reach \$1.2 trillion by 2016.
- ▶ The trend is for large European- and American-based companies to do more research and development (R&D) and manufacturing in emerging markets, where domestic companies are also on the rise.

RESEARCH AND DEVELOPMENT

- ▶ Pharmaceutical R&D budgets are contracting as pharmaceutical industry growth slows.
- ▶ Most large natural products programs, and associated collections overseas, have closed. These include Merck, Bristol Myers-Squibb, AstraZeneca, GlaxoSmithKline, and Monsanto.
- ▶ Around the world, natural products research is more commonly found today in smaller discovery companies, semi-governmental or governmental entities, and universities.
- ▶ In recent years, elements of large pharmaceutical natural products programs were spun off into non-profits, or semi-governmental entities (particularly in Europe), and compound libraries were given away or sold off.



ADVANCES IN SCIENCE AND TECHNOLOGY

- ▶ Significant advances in science and technology make natural products a great deal faster, cheaper and easier to work with than in the past.
- ▶ Scientific and technological advances are also dramatically expanding our understanding of the natural world, including relationships between organisms, and the ways natural products can contribute to human health.

DEMAND FOR ACCESS

- ▶ The need to access 'new' genetic resources is less than in previous years. New research tools mean that diversity found in companies' backyards and existing collections, particularly in the previously inaccessible genomes of microorganisms, can keep researchers busy.
- ▶ Microorganism and marine organism collection programs still continue in some academic institutions and companies, often funded by governments. But field collections are smaller and more limited in scope than previously.
- ▶ With the shift in focus to genes and looking deeper within organisms, and most researchers having easy access to large compound libraries that can now be examined in new ways, the value of large scale collections in high biodiversity areas has been reduced.

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

There have been real and concrete gains under the CBD in the last 20 years. Large pharmaceutical companies support the need to sign agreements, reach mutually agreed terms, and share benefits. However, numerous unresolved issues and concerns remain.

Implementation of the Nagoya Protocol can respond to the following specific concerns expressed in recent years:

Helping researchers and companies follow ABS laws – Many researchers and companies have expressed concern about the absence of guidance on how to navigate ABS measures in many countries. 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 ABS procedures.

Legal certainty and clear, workable regulations – Time-consuming and bureaucratic regulations, and an absence of legal certainty when acquiring genetic resources from some countries, are regarded by many companies as major stumbling blocks in natural products



research. The Nagoya Protocol seeks to address these concerns and create an environment of legal certainty and mutual trust by requiring Parties to designate one or more competent national authorities to oversee ABS permitting and an ABS national focal point to make information available on procedures for obtaining prior informed consent and reaching mutually agreed terms (Article 13).

Building the capacity of governments – Article 22 of the Protocol also calls for building the capacity of governments to effectively implement the Protocol, including the development and implementation of ABS legislation, negotiation of mutually agreed terms, and improved capacity to undertake research on national genetic resources. Article 21 also promotes awareness-raising in all countries.

Defining the scope of ABS measures – Many in industry have expressed concern about the inclusion of biological resources within the scope of ABS measures. The scope of the Protocol, however, does not include trade in commodities, nor local trade or subsistence use. It specifically applies only to genetic resources and traditional knowledge within the scope 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...". Implementation of the Protocol can further help to clarify the issue of scope.

Responding to scientific and technological advances – Advances in science and technology have transformed the use of genetic resources since the CBD entered into force. Implementation of the Protocol provides an opportunity to update and modify previous approaches to access and benefit-sharing to take into account new scientific, technological and business realities.

