Bioactive Agents from Dryland Biodiversity of Latin America

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Bioprospecting of Genetic Resources and Intellectual Property Rights*

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Summary

Why Intellectual Property Law? Protection of intellectual property provides the necessary incentive for an entity to invest in the development of a product. Such protection assures that only the investing company, and not its competitors, may benefit from the financial reward of the investment. Today development of a new pharmaceutical or agrochemical requires such investment that it would be economically unfeasible without such assurance of investment return. Whereas the average United States of America (U.S.) non-pharmaceutical company invests $7,600 in research and development per employee, pharmaceutical companies invest an average of $56,000 in research and development per employee. A new pharmaceutical drug takes an average of 8 to 10 years and $100-200 million to get to market after patenting. The drug candidates that do make it to market must also bear the expenses of those that do not.

This is not unique to the U.S. Studies by The World Bank show that investment by technology based companies in a given country is directly related to the intellectual property protection in that country (Mansfield, E., 1994). Italy, Canada and Mexico have experienced significant growth of investment into pharmaceuticals after their patent protection for pharmaceuticals was strengthene (Mossinghof, G.J., 1996). For example, Mexico changed its patent law in 1991 and saw research and development investment grow from $16 million to $42 million in three years (Mossinghof, G.J., 1996). The ability to protect a proprietary investment is key to all technologically driven industries. Both the U.S. and Chile provide for a patent system in their respective Constitutions.

Nonetheless, concerns remain in many developing countries that pharmaceutical patents will lead to high prices, that their existing regulatory processes are weak, and that rights of indigenous communities or compensation of source countries have not been adequately addressed (Gyllenhaal, C. & McChesney, J. D., 1996).

Types of Intellectual Property

Copyright. According to U.S. Copyright Law, works subject to copyright are original works of authorship fixed in some tangible medium of expression. This includes literary works, software, drawings, photographs, works of fine arts, motion pictures, sound recordings and musical compositions (McCarthy, J. T., 1995). Copyright protection is automatic upon fixation of the work. The works can be registered, but registration is not necessary to obtain copyright protection.

Copyright Laws vary among countries. This variation has been the basis of international trade disputes. The recent, dramatic technological advances in electronic distribution of copyrightable material has produced confusion and conflict among copyright owners and users. The Chilean Constitution provides protection for works of authorship which are artistic and intellectual creations, such protection to extend for a term not less than the life of the author. (García-Huidobro V., 1996)

Patents. In order to be patentable under U.S. patent law, an invention must be (a) new (different

from prior art in its area); (b) useful (practical as opposed to artistic), and (c) non-obvious (not obvious to one of ordinary skill in that field). There are three types of patents in the U.S.: utility patents (compositions of matter, processes, products of manufacture), plant patents (cultivations of new and distinct asexually reproducing plants), and design patents (new, original and ornamental characteristics of configuration, shape or surface ornamentation). Sexually reproducing varieties cannot be patented but can be protected under the Plant Variety Protection Act of 1970 (McCarthy, J.T.,1995).

In Chile, the Constitution protects inventions, models, industrial processes and other analogous creations for a time established by law. Plant varieties are excluded from patentability in Chile. However, Chilean law provides for a special protection to developers of new plant varieties, developed either naturally or through genetic work, providing the variety is (1) new; (2) distinct; and (3) homogeneous or stable (García-Huidobro, V., 1996).

Although much effort has been invested into the harmonization of patent laws among countries as the result of NAFTA and GATT, much work remains to be done. Furthermore, not all countries of the Americas have signed these treaties. A patent in a particular country does not convey protection in another. A "foreign counterpart" must be filed within a statutory period of time after the initial domestic filing and the breadth of such foreign counterpart is dependent on the patent laws of that country. Furthermore, the strength of a patent in any given country is only as good as patent enforcement in that country. Infringement and import laws are critical tools in the implementation of intellectual property protection. "Case law" resulting from rulings on infringement lawsuits develops slowly as such lawsuits are filed and adjudicated.

Trademark. Under U.S. law, a trademark is a word, slogan, design, picture or any other symbol used to identify and distinguish goods. A service mark identifies and distinguishes services rather than products. Trademarks perform four functions; (1) identification: to identify goods in a manner that distinguishes them from those sold by others; (2) source: to signify that all goods bearing a given trademark come from, or are controlled by, a single source; (3) quality: to indicate that all goods bearing the trademark are of an equal level of quality; and (4) advertising: to advertise, promote and generally assist in selling the goods. (McCarthy, J.T.,1995). Chilean law also provides for the protection of commercial marks under its Constitution.

Trade Secret. A trade secret is business information that is the subject of reasonable efforts to preserve confidentiality and has value because it is not generally known in the trade. Such confidential information is protectable against those who obtain access through improper methods or by breach of confidence. Reasonable steps must be taken to preserve the confidentiality of the information, so the burden of protecting a trade secret is that of its owner. (McCarthy, J.T.,1995).

Intellectual Property and Academic Institutions

Unlike commercial companies, educational institutions do not generally deal with all forms of intellectual property protection. For example, since their mission includes the dissemination of information through teaching and publication, universities do not deal in trade secrets. Trademarks (logos) are identifying, approved marks associated with the identity of an entity, and in universities are only commonly associated with athletics.

However, patentable inventions and copyrightable works are produced on an ongoing basis by university faculty in the course of their teaching and research efforts. Many universities now protect such inventions and works by patenting or enforcing copyright to encourage commercial partners to develop such discoveries, thereby making them available to the public.

University owned patents and copyrighted software are also used to attract research funding from commercial sponsors. License rights to such university proprietary property are granted in exchange

for funding, provided the right to publish is retained for the faculty investigator. U.S. federal funding agencies and industry consortia have combined resources to support basic research of commercial interest and to contractually agree on rights to and compensation for intellectual property developed under such funding.

Like other employers, universities in the U.S., and frequently in the rest of the Americas, require their employees to assign ownership to the institution. This is necessary so the institution can comply with intellectual property agreements it may sign in conjunction with funding it receives. Unlike commercial employers, however, a significant percent of any royalties a university receives (up to 50% in some cases) is distributed to the inventor.

Ownership and Licensing

Patents, copyrights, trademarks and trade secrets may be owned by the inventor/author or may be assigned to and owned by another party. Patents provide the patent owner the means to control use of the subject invention by prohibiting others from practicing it without permission. Such permission is usually in the form of a license. A license provides for the use of the invention under defined conditions (e.g., within a defined time, market line or territory), usually in exchange for some payment. A license may be "non-exclusive" to more than one party or may be "exclusive" to a single party for some defined scope (defined time, market line, territory). (McCarthy, J.T.,1995).

Rights to a patent alone do not guarantee the ability to commercialize the subject invention. Other approvals, such as regulatory approval may also be necessary. More and more frequently multiple licenses (non-exclusive, as well as exclusive) are required from different owners to gain all rights necessary to commercialize a single product. This is particularly true in pharmaceuticals and biotechnology.

Bioprospecting and Intellectual Property

With the recent interests in "bioprospecting", there has been great debate over appropriate mechanisms to reward all participants in the identification, development and commercialization of resulting novel materials. The controversy has been three-fold: (1) identifying the key contributors; (2) attempting to understand the scope of the total endeavor; and (3) understanding the relative value of the efforts of each contributor to the total endeavor.

Recent attempts to patent DNA sequences with unknown functions, human cell lines, and transgenic animals have accelerated the controversy over identifying true contributors to an invention (Gross, N. & Carey, J., 1996). The controversy over appropriate recognition and compensation often results from the lack of familiarity on the part of one contributing sector with the others' skills and contributions. Other aspects of the controversy are more fundamental disagreements on what should be patentable. Scientific techniques enabling these "inventions" of genes, novel cell lines and transgenic organisms are developing much more quickly than statutory and case law regarding their commercial use.

The complementary skills necessary for new inventions from bioprospecting may best be protected by a variety of laws, including, but not limited to intellectual property laws. For example, collection of material in a conservationally responsible manner may be the subject of collection permits. Access to those collections either directly or through indigenous people, can be addressed by contractual agreements subject to local contract law. Identification of novel materials and large scale production of the active component(s) from the natural source may be subject to patent protection. Efficacy and toxicological testing of the active component in carefully controlled animal and human studies may be subject to regulatory approval. Assessment of economical feasibility of commercialization, including marketing strategies, may be subject to trade secret and trademark protection. Although the

patented invention is key, without the financial investment and legal protection required for regulatory approval and marketing, a new pharmaceutical or agrochemical will never become available for use.

A combination of these legal rights can be achieved contractually. However, to do so equitably requires a knowledge of real and intellectual property, contract law, and national laws. It also requires some knowledge, usually based on experience, of the financial investments and benefits required to encourage all contributing parties to come to an agreement over these rights.

Some countries are attempting to construct guidelines for research on their genetic materials. For example, the Bioresources Development and Conservation Programme (BDCP) of Nigeria has developed a model which includes the following features: (1) economic benefits channeled back to the area where the source plant was collected, (2) requirement for Nigerian scientists to be involved in all aspects of drug development, (3) project objectives to include standardization of local phytomedicines, (4) recognition of the need for alternatives to intellectual property rights to protect the traditional heritage of rural communities, and (5) prioritization to drugs that treat diseases endemic to the tropics. (Gyllenhaal, C. & McChesney, J. D., 1996). Other policies exist in Australia and are under development in Malaysia and the Philippines. (Gyllenhaal, C. & McChesney, J. D., 1996).

This NIH/NSF/USAID ICBG

The NIH/NSF/USAID ICBG, in which The University of Arizona (UA) of Tucson, Arizona (USA) and Pontificia Universidad Catolica de Chile (PUC), Santiago, Chile, are collaborators, along with other institutions in Argentina, Mexico, and the U.S., required agreements among the collaborators to protect inventions developed under the Program and to address equitable distribution of any revenue resulting from the commercialization of those inventions. Since bioprospecting models for equitable reward systems are largely untested, we have relied on standard licensing terms with the commercial partner (a royalty payment based on percentage of sales) combined with contractual agreements for the distribution of that royalty, should there be any, with the collectors, the inventors and appropriate conservation programs.

The United States has one of the more developed patent systems in terms of patent law and case history, particularly in the area of pharmaceuticals. Patent applications for inventions developed under the ICBG will be filed first in the U.S. and inventorship will be determined by U.S. patent law. (McCarthy, J.T.,1995).

The work scope of UA’s ICBG Program does NOT include development of genes or transgenic plants as products. Living materials will be retained in the country of origin; only extracts or dried plant materials will be used as sources of further purification and characterization of bioactive ingredients. Therefore, the issues of concern focus solely on traditional pharmaceuticals/agroproducts and the equitable financial recognition of all contributing team members responsible for their development.

Royalties will be divided into a "collector’s share", an "inventor’s share" and a "conservation share". The employing institutions of all named inventors of a patent will divide the "inventors share" (45% of all royalties). The collector will receive a separate "collector’s share" (5%) and the remaining (the largest) share (50%) will be distributed to a conservation fund in the area of the collection of the country of collection.

While the adequacy of this distribution plan is somewhat speculative at this time, given the unknown characteristics of the yet-to-be developed product, it was negotiated with all of the seven collaborating entities and contractually agreed upon. Hopefully, it has sufficient flexibility to allow for adjustments to a specific product while providing incentive and independence to the participants.

It allows the commercial partner to set a sales price to recover its substantial investment, and allows for the participation of other contributors based on that sales price.

The most difficult compensation to define is that intended for conservation and sustainable agricultural programs. It would be presumptuous of individuals from outside the collecting country to identify priorities for that country. Therefore, while the ICBG provides for study of these conservation and sustainable agricultural issues, the actual planning and implementation of programs will be through ICBG participants from the countries of collection.

Possible Outcomes

It is important to realize that the probability the ICBG will develop a commercially viable drug is quite small. The Pharmaceutical Research and Manufacturers of America quotes data indicating that for every drug approved for commercialization and made available to the public, 5000 compounds were synthesized and screened (Mossinghof, G. J., 1996). Leads from the ICBG's may have a higher success rate, but the probabilities are still quite low. Therefore, the real benefit from the ICBG is in the collaborative interactions established among the participating countries, the data bases developed as a result of the project and the training of students and faculty through exchange programs. For example, training in the chemical analysis skills necessary for the identification and characterization of new product leads under the ICBG can be applied to other national needs, such as environmental assessment and regulation.

As the world becomes increasingly multinational in its industry, trade, politics, and academics, the value of such shared skills and collaborative interactions is of growing importance.

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