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World Patent Information 29 (2007) 255–261

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Poisons and politics – Indigenous rights and IP protection ☆

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Abstract

There is a heightened awareness worldwide of the importance of pharmaceutical materials derived from naturally occurring organisms, particularly plants found in the tropics. In this context, the article explores the practical and political aspects of the interface between the indigenous rights relating to the traditional knowledge of such 'natural medicines' and the interests of the countries and companies that build on that knowledge in providing widely available and improved medicines. The article refers to traditional knowledge databases and looks at two regimes of prior informed consent and benefit sharing, the contractual and disclosure approaches. Many of the key issues are highly political, with developed and developing countries having widely different approaches. The article concludes that many of these issues are likely to run for many years before being fully resolved.

Keywords: Indigenous rights; IP protection; Biological diversity; TRIPS; WTO; WIPO; Prior consent; Benefit sharing; Contractual approach; Disclosure approach; Traditional knowledge; Genetic resources; Databases; Database inventory

1. Introduction

Plants and animals have long been used by indigenous people as a source of medicines and poisons. In the West pharmacy was essentially born out of the herbalist's art. The natural world is full of plants, animals and microbes that use natural toxins for defence and the capture of prey. Many of these toxins have been honed by hundreds of millions of years of evolution to be exquisitively specific for their biological target; indeed many of these compounds are amongst the most toxic compounds known to man, such as botulinum toxin (*Clostridium botulinum*), ricin (castor bean), tetrodotoxin (puffer fish), conotoxin (cone-snail) and Poison Arrow Frog venoms. Very many of these compounds when isolated from their natural host have been the basis for new classes of treatment and the source of insights into the cellular functioning of the body. Notable examples include the anti-cancer drug taxol derived from the bark of the Pacific Yew (*Taxus brevifolia*) and the immunosuppressant and potential anti-cancer treatment rapamycin derived from the *Streptomyces hygroscopius* mould found on Rapa Nui (Easter Island).

In the last two decades or so, there has been a great deal of effort within the pharmaceutical industry to identify potential lead compounds by testing combinatorial chemistry libraries against biological targets using fast throughput screening techniques. There are some who would say that the results of this enormous effort have been comparatively disappointing. Part of the explanation for this comparative lack of success has been that many of the compounds originally tried were not sufficiently ''drug-like'' and lacked the structural complexity which is seen in many biologically active compounds.

There is now something of a revival in the so-called ''rational'' pharmacology. Advances in genomics and proteomics (which allow researchers to understand the biological target structure) are now increasingly being allied to the search for biological actives from flora and fauna to find ligands for those sites. By far the greatest reservoir of biodiversity and of biological ''toxins'' exists in the tropics. Over the last couple of decades countries in the developing world have been progressively growing in awareness of the

☆ Previously published in The CIPA Journal, Vol. 35, Issue 7 (July 2006), pp. 472–477.

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0172-2190/$ - see front matter
doi:10.1016/j.wpi.2007.02.001

importance of their biological "treasure trove". Increased activism and political confidence in the developing world, allied to the reawakened interest of Western medicine in plant- and animal-derived compounds, will likely make for a turbulent interface between the classical protection of intellectual property rights and the assertion of aboriginal rights. In this article, the authors give a brief tour of the complex (and often acronym-ridden) political landscape.

2. The Convention on Biological Diversity

Where one looks to exploit the naturally occurring compounds of a region, one is rarely presented with a *tabula rasa* – there is often a complex web of asserted rights. Given the vast number of potential plants one can investigate, workers in the field are often directed to a particular species on the basis of traditional knowledge. Indigenous people will very likely be naïve as to the nature of the compound in the plant and to how biologically it has its effect. They will, however, likely be the guardians of generations of tradition of which plants are good for which ailments, when and where the plants are best harvested, how best the plant should be administered to the patient and what side effects should be expected. How does one value and define such knowledge within a "classical" IP framework? In some senses the information is in the public domain but in other senses it could not be said to be part of the understanding of broader humanity. To what extent will this type of indigenous knowledge contribute to an invention or invalidate it? Separate from questions of patentability, should the traditional knowledge attract some parallel right or reward for the holders of such knowledge? Where plant samples are taken away for propagation elsewhere or where the genes from these plants are extracted and inserted into other organisms who should own the rights, if any, in those genes? These are potentially divisive questions.

It might be said that there has been a general trend over the past two decades or more away from the idea of "common" ownership of biological/genetic resources towards proprietorial intellectual property rights (IPR). The International Undertaking on Plant Genetic Resources adopted in 1983, which focussed on access to plant genetic resources for food and agriculture, was originally "based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction" [1]. In November 1989, the agreed interpretation of the Undertaking made clear that "free access" to genetic resources did not mean "free of charge" [2] and by 1991 the Undertaking recognised "that nations have sovereign rights over their plant genetic resources" [3].

Echoing this, the 1992 Convention on Biological Diversity (CBD), promoting the conservation and sustainable use of biological diversity, recognised that states have the "sovereign right to exploit their own resources according to their own environmental policies". The CBD introduced several key themes/principles which have informed and influenced the debate on the protection of the rights of developing countries and their indigenous communities since – namely, states should respect, preserve and maintain the knowledge and practices of their indigenous people, access to genetic resources should be subject to prior informed consent and there should be a fair and equitable sharing of the benefits arising from commercial or other utilisation of such genetic resources. The CBD also recognised that access and transfer of technology, that is subject to patents or other IPR, should be provided on terms which recognise and are consistent with the adequate and effective protection of IPR [4].

These issues are now firmly on the international political agenda. The United Nations has a Permanent Forum on Indigenous Issues and the World Intellectual Property Organization (WIPO) has established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), both of which address intellectual property right protection issues in the developing world. Ongoing negotiations on the protection of intellectual property rights of developing countries are being pursued at WIPO and the World Trade Organization (WTO).

Recently, a draft Protocol to the CBD on access and benefit sharing was filed by Ethiopia on behalf of the African Group of countries [5]. The Protocol envisages that prior informed consent should be a pre-requisite to the use of biological resources and community knowledge and that fair and equitable benefit sharing should flow from any commercial application of such knowledge or resources. An annual royalty equal to half the net profit from commercialisation has been proposed. Moreover, the provider of the biological resource would retain ownership of it (and of any modifications to it or to its biochemical or genetic components) and constraints would be placed on the transfer of ownership. The Protocol remains on the agenda of the CBD for further investigation and will form part of the subject matter for discussion at the tenth CBD meeting in 2010. It is a fair comment to say that the content of the Protocol is controversial, particularly from the perspective of the developed nations and their industrial sectors who are likely to view it as an impediment to innovation and a considerable disincentive to investment in developing countries.

3. TRIPS and the CBD

The necessity for trade and its associated demands on biological resources means that the CBD cannot be considered in isolation.

The Trade Related Aspects of Intellectual Property (TRIPS) Agreement is often described as one of the three pillars of the WTO (the other two being trade in goods and trade in services). It places the protection of IPR at the heart of international trade and obliges WTO members to comply with certain minimum standards for the protection of IPR, although it is not prescriptive as to how the compliance measures should be implemented by individual WTO members.