

DISCUSSION PAPER

Biodiversity-based Patent Term Extension: An Opportunity for Using the Existing IP System to Support ABS

Jock Langford¹. Senior Policy Advisor, Intellectual Property Rights, Biodiversity Convention Office, Environment Canada. Email: Jock.Langford@ec.gc.ca

There is a need for an open discussion of the potential role of existing IP rights in achieving the Convention on Biological Diversity's objectives – conservation, sustainable use and equitable benefit-sharing. The following discussion is limited to patent terms.

In a knowledge-based economy, innovation processes take on many of the characteristics of the production processes of the industrial economy. From this perspective, the innovation value chain consists of various inputs – raw materials, information/science/knowledge, informatics, capital, labour – which are employed in the development and marketing of an innovative commercial product or process.

The biodiversity-based innovation value chain may consist of; inter alia, biological resources, genetic material, traditional knowledge, taxonomic/genomic/proteomic information, basic and applied science, proprietary R&D, regulatory approval research, IP protection and marketing expenditures.

In general, the existing intellectual property system provides protection in support of investments in inputs in the latter stages of the biodiversity-based value chain such as patents/plant variety rights/trade secrets, regulatory data protection and trademarks/trade dress. Currently, however, there is little IP protection at national or international levels afforded upstream inputs in the value chain.

Under the Convention on Biological Diversity (CBD), Parties agreed to principles for recognizing the sovereign rights of Parties over their genetic resources and principles governing access to and use of the traditional knowledge of indigenous and local communities. Several countries have begun to implement Article 15 (Access to Genetic Resources) and Article 8(j) (Traditional Knowledge) under national law. These laws are in effect new forms of *sui generis* property rights.

The international ABS regime will necessarily entail both higher costs for use of some inputs in the value chain – genetic resources and traditional resources – and new regulatory and transactions costs associated with obtaining prior informed consent and negotiating mutually-agreed terms. Scientists and industry can view ABS in two ways. In the short-term, ABS policy

¹ The views expressed are solely those of the author.

will increase input and regulatory costs. In the long-term, ABS policy will help conserve a critical input for sectors using biotechnology.

The pharmaceutical industry context for negotiating an international ABS regime is that the high cost of clinical trials to prove safety and efficacy is inflating drug costs and there are growing pressures from many governments to control health care costs (including drug prices). The high cost of drug regulatory approval is dominating the cost structure of the pharmaceutical industry and in the end will greatly affect the ability of the drug industry to allocate additional rents to other inputs including genetic resources. Outsourcing of clinical R&D to developing countries should provide some cost relief in the coming years and if this is the case the future cost structure may afford more opportunity for providing compensation for accessing and using genetic resources.

From a CBD perspective, ABS instruments leading to a higher valuation of genetic resources are desirable if benefit-sharing leads to in-situ conservation and sustainable use of biodiversity. A shared goal is to minimize the regulatory burden of any ABS regime but realistically there will be some new administrative and enforcement costs associated with this regulatory and property rights regime. Perhaps the nature and level of administrative and enforcement costs of intellectual property rights are useful for comparison's sake when designing an ABS regulatory system.

There are some additional economic challenges facing ABS policy-makers that patent term extensions may have a potential role in addressing:

- Firstly, biodiversity-based innovation must compete with other drug discovery pathways such as combinatorial chemistry and human genomics. An ABS regime that increases the cost of genetic resources risks providing a disincentive for biodiversity-based research and as a result existing biodiversity-based investment may shift to other innovation pathways. Patent term extensions have been used to compensate for investments in the public interest; for example, US patent term extensions to encourage paediatric clinical research. Patent term extensions can be justified for biodiversity-based research to support society's environmental and health goals since the preservation of species is in effect protecting our future "medicine cabinet". Patent term extensions for biodiversity-based research would lead to a shift away from other innovation pathways towards ABS-related investments, thereby creating economic incentives for governments and stakeholders to reduce the rate of loss of species. The financial cost to society of biodiversity-based patent term extensions would be deferred for 20 years when the patent extension term begins.
- Secondly, the biotechnology and pharmaceutical sectors are competing (albeit poorly) for biological resources against resource sectors (e.g. forestry products). Conserving species and ecosystems is essential for ensuring that genetic resources will be available for biotechnology and pharmaceutical research by future generations. Currently, the value of timber per hectare far exceeds the current market value of genetic resources per hectare. When it comes to preserving genetic resources, market conditions and incentives and resource management practices are highly skewed in

III. Specific Issues for consideration in the elaboration of the IR:
Interface with Existing IP Systems & Limits and Opportunities for Existing IP Rights

favour of the resource sector over the biotechnology and pharmaceutical sectors. While there are strong long-term interests for the biotechnology and pharmaceutical sectors to actively support the conservation of genetic resources, to date these sectors have not actively engaged in the public policy debate. Unless there are new innovative market incentives and/or significant government conservation measures many of the world's species will be lost during the next 50 years. Biodiversity-based patent term extensions may be part of the solution. Patent incentives that support foreign direct investments in biodiversity-based research should also provide an incentive for governments to take additional measures to conserve biodiversity.

My support for biodiversity-based patent term extensions is qualified. User country measures, new *sui generis* rights or other measures, which will help ensure benefit-sharing from the use of genetic resources and traditional knowledge, will be necessary to ensure that additional rents resulting from patent term extensions are appropriately distributed to upstream inputs in the biodiversity-based innovation value chain.