Natural Products and Pharmaceutical Innovations: What are the Patent Options?

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Natural products play an important role in pharmaceutical innovation. They are active components in many medicines. For example, nearly half of the small molecules used to treat cancer are natural products or directly derived from natural products.[1] They are also components of vaccines.

The pharmaceutical industry is constantly seeking access to natural products and the traditional knowledge associated with them. These include plants (roots, bark, leaves), micro-organisms (terrestrial and marine), toxins, venoms and other natural biological agents.

In the current race to develop a drug and/or vaccine against COVID-19, natural products or derivatives are surely worth considering as a starting point.

The harvesting of natural resources for use by the pharmaceutical industry is usually carried out by partners such as traditional healers, farmers, academics or businesses. Thus, the process usually involves several stakeholders, including providers and users of natural resources and associated traditional knowledge, which are often located in different parts of the world.

Fair and equitable collaboration in such a context requires well-developed collaboration agreements and access and benefit-sharing agreements. Various instruments of international law encourage the signing of such agreements, including:

> The Convention on Biological Diversity (CBD), which recognizes the sovereignty of states over their natural resources. The CBD sets out fundamental principles to regulate access and benefit-sharing, including that access to natural resources, their use and the sharing of benefits arising from them should be based on “mutually agreed terms.”[2]
> The Nagoya Protocol covers the sharing of the results of research and development, the payment of royalties and

joint ownership of intellectual property (IP) rights.[3]
The World Intellectual Property Organization (WIPO) has developed a guide to assist providers and users of natural resources and associated traditional knowledge in the negotiation and establishment of IP clauses in access and benefit-sharing agreements. The guide describes how IP rights can be exploited and managed to achieve the desired objectives, and how the benefits arising from the use can be created and shared in a fair and equitable manner, thereby promoting the conservation and use of biodiversity.[4]

Furthermore, research and development activities in the pharmaceutical industry are known to be associated with high risk and high investment costs. Indeed, it is widely recognized that the process to develop a drug can take up to 15 years, only about 16% of molecules entering the clinical phase will be approved, and only 1 in 5 marketed drugs generates revenues equal to or greater than the research and development costs involved.[5]

In the pharmaceutical industry, intellectual property, especially patents and data protection, is thus considered an essential instrument for securing the economic benefits of an innovation.

Efforts in this intense period of development of a drug/vaccine against COVID-19 are of course focused on the technical aspects directly related to research and development. Nevertheless, those involved should not lose sight of the importance of collaboration agreements and access and benefit-sharing agreements.

When it comes to natural products in particular, concluding agreements with solid clauses on possible innovations and patents is key for providers of natural resources and traditional knowledge. The same applies to users of these resources and knowledge. We explore some of these clauses below.

Initial consideration – deciding whether or not to patent

Factors to be considered include the nature and purpose of the project, the expected value of the project results, business objectives, and the ability to manage acquired patents. The decision to apply for a patent, or not to do so, depends largely on whether the benefits of patent protection will outweigh the cost of obtaining it.

Confidentiality

What information must be kept confidential to ensure that its disclosure does not jeopardize the chances of obtaining patent protection? Agreements should include clear clauses on information management (publication of scientific articles, presentations at conferences, press releases, etc.). The parties may agree to make public disclosures only after mutual approval and the filing of a patent application. Some jurisdictions (Canada, United States, Japan) offer a grace period after a disclosure of the innovation, but for other jurisdictions (Europe, China) there is virtually no such grace period. Where patent protection is desired, the US Provisional Patent Application is a key tool for managing the confidentiality of an innovation under development.

Patentability of research and development results

While a natural substance as such generally cannot be patented, some results derived from the use of natural resource and associated traditional knowledge can be protected by patent, provided that the innovation is new, useful and not obvious.

Parties obtaining the patents

Should a general principle applicable to all innovations resulting from the use of natural resources obtained from providers be adopted? Should users have the obligation of reporting all developed innovations? Should they have the obligation of agreeing on the terms for obtaining a patent?

Countries where patent protection can be obtained

Countries where patents can be obtained are determined by taking into account key markets, strategic locations for drug manufacturing and other considerations, such as the country of origin of natural resources and the traditional knowledge associated to them. Depending on the number of countries ultimately chosen, a strategy involving a Patent Cooperation Treaty (PCT) international application could be considered.

Inventors

It is important to name the “real” inventors in a patent application—the validity of the future patent could depend on this. Those who participated only in collecting natural resources or verifying use results may not qualify as inventors. The extent of scientific contribution is one of the main factors to consider.

Ownership of future patents

The Nagoya Protocol mentions joint (provider-user) ownership of patents as a possible benefit-sharing mechanism. However, companies in the pharmaceutical industry are not keen on this practice. They try to avoid the complications and legal uncertainties associated with joint ownership. Although most countries, including Canada, require the co-owner of a patent to obtain the consent of the other co-owner in order to grant a license, this is not the case in the United States, where a co-owner can grant a license without the consent of the other party and without having to give any justification with respect to royalties or other payments.

One commonly adopted solution allows the user to retain ownership of the patent while the provider is granted a royalty-free license. However, some providers consider this option unfair because the patent is not co-owned.

In cases of joint ownership, it will of course be necessary to determine how responsibilities will be divided between the provider and user. The parties must decide who will be responsible for filing the patent application and for maintaining the continuing effect of the patent, and who will provide the resources necessary for performing these actions.

Patent exploitation

What is the most appropriate model for exploiting a patent and disseminating innovation? Which among a license, assignment or joint venture is preferable? Who will negotiate and approve the terms of any subsequent patent exploitation agreement? Should licenses be granted free of charge, or should preferential conditions be granted to entities in the provider’s country or to other partners?

Benefit-sharing

How, when and between whom will the monetary or non-monetary benefits arising from the commercial exploitation of a patent be distributed? What benefit-sharing mechanisms can be applied in this case?

Management of conflicts between provider and user

It is important to determine what jurisdiction will apply and how possible conflicts will be resolved (mediation, binding or non-binding arbitration, civil action, etc.).

Disputes

Only a patent owner can sue for infringement. If the patent is owned only by either the provider or the user, the other party’s cooperation can be negotiated.

End of collaboration

A collaboration can end for a number of reasons, for example, as a result of problems with the flow of natural resources (volume, quality). What happens to acquired patents then?

Conclusion

Providers and users of natural resources and associated traditional knowledge should carefully consider their relationship ahead of time. It is very likely that research and development using natural resources will lead to patentable innovations. If there are no plans for patent co-ownership, it is important to include relevant clauses in agreements that ensure a fair and equitable distribution of monetary or non-monetary benefits resulting from the commercial exploitation of patents.

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1. Newman D. et Cragg G., "Natural products as sources of new drugs over 30 years from 1981 to 2014", *Journal of Natural Products* (2016), 79.3, 629-661.
2. Convention on Biological Diversity.
3. Nagoya Protocol.
4. World Intellectual Property Organization (WIPO) (2018), A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements.
5. Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches (UNEP/CBD/WG-ABS/7/2).