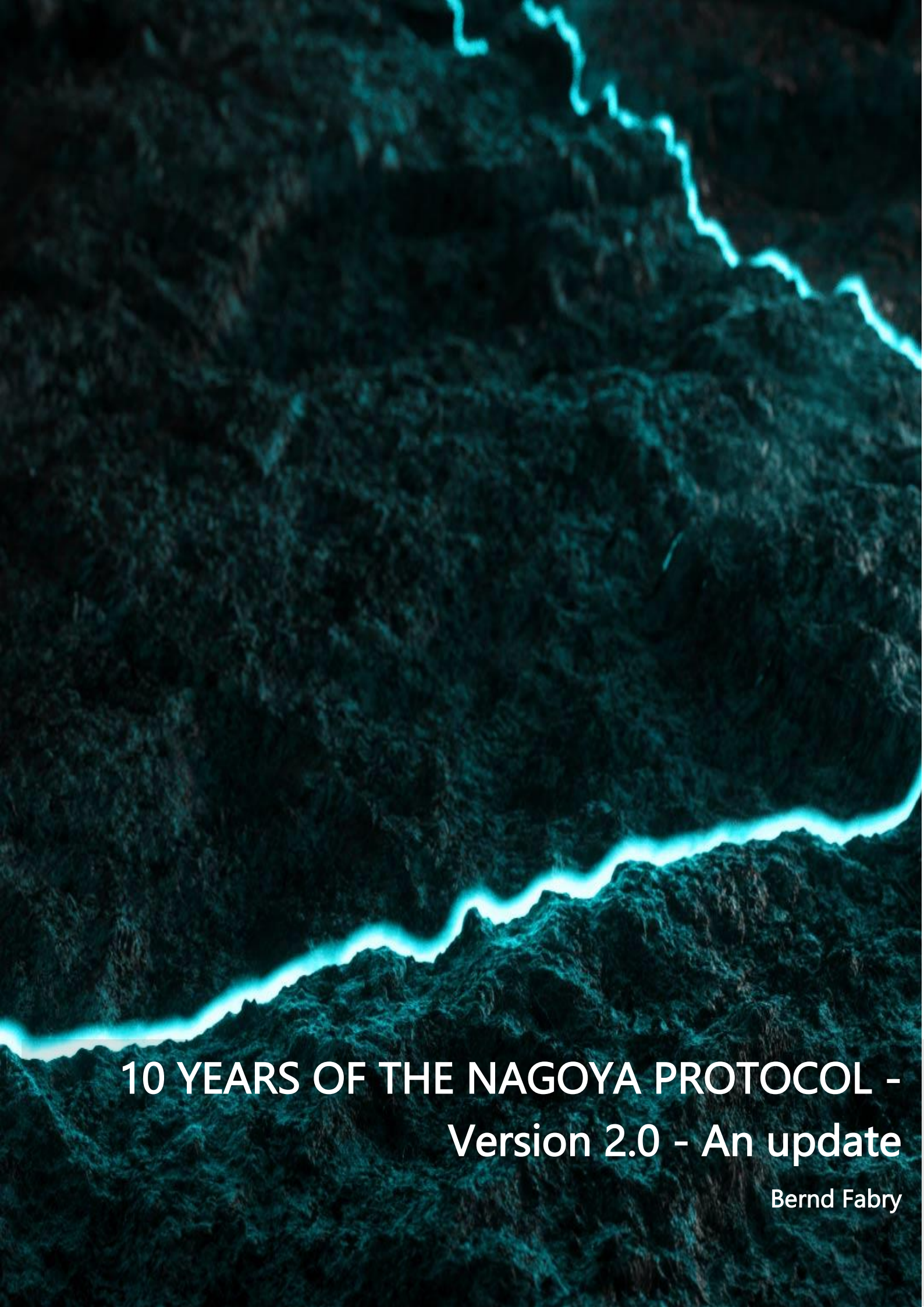

10 YEARS OF THE NAGOYA PROTOCOL - Version 2.0 - An update

Bernd Fabry

10 years of the Nagoya Protocol

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10 years after the Nagoya Protocol entered into force, the balance sheet is sobering. Despite a comprehensive set of rules, only a fraction of the money that was hoped for has reached the provider countries of genetic resources and traditional knowledge.

What remains is the implementation of the Nagoya Protocol into national law, which varies greatly. The EU regulation also specifies which exceptional circumstances may exist that do not require such self-disclosure. Now, a WIPO conference has agreed on certain measures to put the protocol in practice. Let's see where that takes us.

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Introduction

The Nagoya Protocol is part of the biodiversity targets formulated for 2020, which should define the framework for the conservation and sustainable use of biological diversity. In particular, the agreement concretizes Art. 15 of the Convention for Biodiversity (CBD) with regard to access to genetic resources and traditional knowledge and the fair and equitable sharing of the benefits arising from their use. We have already recently reported on the different ways in which the Protocol's guidelines have been transposed into national law, the subordinate consideration given to the protection of intellectual property and the rather sobering conclusions that can be drawn from this to date (see our White Paper on the Nagoya Protocol). Now, well over 100 delegates from the PCT member states have agreed on a treaty that is ready to be signed, which is intended to set uniform standards for patent applicants and, for the first time, also provides for sanctions for non-compliance.

“Groundbreaking” and ‘Outstanding’?

From May 13 to 20, 2024, a WIPO diplomatic conference was held in Geneva to decide on the further procedure for the protection of intellectual property in connection with genetic resources and traditional knowledge and to implement it in an international convention.

Expectations were high, and the WIPO, which was in charge of the conference, was not sparing with superlatives: the treaty was “outstanding”; the delegates “applauded and cheered” after its adoption. For the first time, a treaty had been adopted “that deals with the interface between intellectual property, genetic resources and traditional knowledge, and the first WIPO treaty that contains provisions specifically for indigenous peoples and local communities”. According to the President of the Diplomatic Conference, Ambassador Guilherme de Aguiar Patriota, who is also Brazil's Permanent Representative to the World Trade Organization.

However, as is often the case when political representatives give themselves a particularly positive testimonial, it is worth taking a look at the details of the treaty, which is entitled

“WIPO TREATY ON INTELLECTUAL PROPERTY, GENERIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE”

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High ambitions - perhaps too high?

Article 1 states that the purpose of the treaty is nothing less than to improve the efficiency, transparency and quality of the patent system - presumably worldwide - and to prevent patent protection for inventions that are not new or not inventive with regard to genetic resources or traditional knowledge.

For the patent expert, this statement does not seem well thought out. It starts with the fact that patent protection is a national, at best a regional matter. The claimed nationwide effect could therefore only occur if the treaty provided for instruments to transpose its provisions into national law. However, this is not the case. Article 7 merely provides for the International Patent Cooperation Union to be requested to supplement the PCT with corresponding

regulations. Everything else is the responsibility of the individual member states.

Furthermore, inventions based on the aforementioned genetic resources or traditional knowledge are not automatically patent-ineligible for this reason alone. The development of a medicinal product from an indigenous plant or with the help of shamanic knowledge, for example, may very well be new and inventive and would still violate the principles of the Nagoya Protocol. The scope of the claim is therefore too narrow, which is also objectionable elsewhere.

Digital Sequence Information

It is worth reading Article 2 very carefully, even if it comes across as a rather inconspicuous collection of definitions. The "bombshell" is in the definition of the "source of genetic resources". In addition to the known sources of genetic material such as research centers or local providers, gene banks are now also mentioned. This incidentally closes a much-discussed loophole in the Nagoya Protocol regarding "Digital Sequence Information". Using DSI, the genetic diversity of species can already be comprehensively characterized today and genetic material can be used without ever holding it in one's hands. It is currently assumed that there are around 12,000 listed plant substances, compared to over 100,000 substances that nature still has in store and for whose synthesis digital sequence information may already be sufficient.

This is why the importance of digital information on genetic and biological resources has increased so much in recent times. The USA, the EU and Japan in particular have set themselves the goal of enabling open source access to this data. It has been assumed for some time that developments based on DSI should be evaluated in a similar way to the use of specific genetic resources. With the present agreement, the conference has also decided on this issue.

Obligations and sanctions

Article 3 stipulates that patent applicants are obliged to name the country and origin of the genetic resources or traditional knowledge used or, alternatively, at least indicate the source. If this is also not possible due to a lack of positive knowledge, a corresponding

declaration must be made. The examining authorities are not obliged to check the truth of the information. The provisions also do not apply to existing patent applications.

However, it should be noted here that the Nagoya Protocol and national law based on it already contain corresponding provisions. It is therefore unclear to what extent these new provisions are intended to improve or even change the situation.

Another unanswered question is the threshold at which the obligation to provide information applies. Is the disclosure only mandatory if the resource is relevant to the invention or must information also be provided, for example, on subordinate formulation components? What about resources that were already obtained before the agreement came into force and are now being reused? Unfortunately, the clarifications of the Nagoya Protocol on these questions have not been included in the treaty.

Article 5 contains the possibility for the declarant to correct incorrect information. However, the examining offices are to be given the option of rejecting a correction if it is based on a deliberately false statement. However, the text of the agreement does not answer the question of how this is to be proven and who is responsible for providing evidence.

On the other hand, applicants who fail to state the origin of their knowledge or make false statements - whether intentionally or not - are threatened with revocation, invalidation or unenforceability of their IP right, whereby these measures can also be imposed retrospectively, i.e., after grant.

Here, too, questions arise for the specialist. For example, there is no reference to the fact that penalties can be imposed during the examination procedure, as this would have required the inclusion of rejection among the sanctions. It is also unclear how the sanctioning process should work: it would make sense for it to be part of the examination procedure, but according to the wording, these are all measures that only take effect after they have been issued. This either reveals a lack of knowledge about the process of examining a patent application or the text has been worded very carelessly.

Summary

The treaty regulating the protection of intellectual property, which includes genetic resources and traditional knowledge, cannot be called groundbreaking. Much, such as the obligation to provide information, is already regulated in the Nagoya Protocol and has since been transposed into national law. Specific sanction provisions are new, but they have been formulated so carelessly that they leave practitioners with more questions than answers. On the other hand, the delegates have almost incidentally removed the Digital Sequence Information as a free source of reference outside the Nagoya Protocol.

The decisive disadvantage of the protocol, namely that it has not been ratified by important states such as the USA or Russia, is presumably being perpetuated here. This treaty also has no international effect, but only contains a request to the member states to incorporate the specific regulations into the PCT - so there is still a long way to go before it is transposed into national law, for which WIPO has no authority to issue instructions. First of all, the treaty needs to be signed by 15 member states in order to come into force.