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Global Enforcement of the Nagoya Protocol in Life Sciences Industries

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Food, Drug, and Device

In October 2014, the Nagoya Protocol entered into force. It created a new international regulatory system affecting all life science companies that conduct R&D on biological material such as animals, seeds, flowers, viruses, fragrances, flavonoids, essential oils, enzymes, yeasts, and so on. So far, compliance by companies is progressing slowly due to unawareness of the regime and uncertainty over its requirements.

By January 2017, this new international agreement will be in force in 89 countries, including China, India, Mexico, Switzerland, South Africa, and the entire EU. Between December 4 and 17, 2016, the second "COP-MOP" takes place. At that meeting, the parties to the Nagoya Protocol are working to accelerate substantive implementation and enforcement of the rules.

This client alert provides an update on the rules enforcing the Nagoya Protocol adopted around the world. By focusing on a selection of national enforcement mechanisms, this alert provides a practical illustration (and reminder) of the need to assess whether R&D and product development pipelines are affected by these new rules.

How the Nagoya Protocol Works

The full title of the Nagoya Protocol to the Convention on Biological Diversity reads "…on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization." Under the Protocol, the Parties **may** adopt (i) provider-country measures on "access and benefit sharing" (ABS), but **must** adopt (ii) user-country rules to enforce compliance with provider-country measures.

(i) Provider-country rules are most relevant for countries rich in biodiversity such as India, Denmark (Greenland), France (mainly through the overseas territories), Brazil, and South Africa. First, as "providers" of genetic resources, countries may require a public permit to obtain them from their territory. Such a permit commonly describes what genetic resource may be acquired, and whether the results of R&D may be commercialised. Second, countries may require the negotiation of a contract with public or private entities on how benefits from R&D on the genetic resources will be shared. Monetary benefit-sharing can include payments into a public fund or making the resulting product available at a preferential price. Non-monetary benefit-sharing can include providing access to scientific results of the R&D.

(ii) User-country rules are most relevant for countries with advanced technological capabilities, where public and private entities conduct R&D to develop commercial products from genetic resources. Under the Nagoya Protocol, all parties must adopt enforcement measures to ensure

that genetic resources used in their jurisdiction have been acquired in compliance with rules of the country that provided them.

The Nagoya Protocol covers “genetic resources” and “associated traditional knowledge.” Both are legal terms subject to controversy. Nevertheless, the following examples likely fall within the scope.

- Black cumin seeds and the derived compound *thymoquinoe* with properties that reduce food allergies;
- pineapple stem and the derivative *bromelain*, a proteolytic enzyme used as the active ingredient in an EU-approved medicinal product to treat burn wounds, and;
- flower buds of the Japanese Pagoda Tree and the derived flavonoid *rutin* with properties useful in hair and skin cosmetics. In Asian traditional medicine the Pagoda Tree is mentioned for its hemostatic effects, possibly qualifying as “associated traditional knowledge” under the Nagoya Protocol.

In the span of two years, the Nagoya Protocol has created a complex web of public rules and private contracts spanning almost one-hundred provider and user countries.

Rules in Provider Countries

South Africa

This country defines bio-prospecting broadly, maintaining a system of notifications and permits that distinguish between the discovery and commercialisation phases of R&D on “indigenous” biological resources. Foreign entities can only apply for a permit jointly with South African entities. With the recent amendments of May 2015, bio-prospecting and bio-trading without a permit can be fined by up to five or even ten million rand (around 700,000 USD), or a fine “equal to three times the commercial value of the activity in respect of which the offence was committed, whichever, is the greater.” (Regulation 42(2)).

China

China generally takes the approach that genetic resources should be restricted to use in China, and the research should include the participation of a Chinese party. Furthermore, China encourages the parties to these sino-foreign cooperative research projects to register the intellectual property of the inventions emerging from that research in China. In relation to the Nagoya Protocol, China’s Ministry of Environmental Protection led a number of other government ministries in issuing a Notice on Enhancing the Access and Benefit-Sharing of Biological Genetic Resources in the Cooperation and Communication with Foreign Parties in October 2014. This Notice requires government approval for foreign parties (1) bio-prospecting in natural conservations and (2) to remove certain of those resources deemed highly valuable from China. Plans are underway to issue a more detailed regulation on acquiring and utilizing genetic resources in the near future.

India

India imposes access requirements on “biological resources” for research and commercial purposes on entities that are not incorporated in India. Authorisations from the National Biodiversity Authority may be required (i) to obtain biological resources from India, (ii) to apply for a patent on results of R&D on the resources, or (iii) to transfer the biological resource as well

as the results of the research. The National Biodiversity Authority may oppose the grant of IP rights linked to Indian biological resources or associated traditional knowledge. Indian law grants the authority the power to do so around the globe.

France and French Guyana

In August 2016, a new French law entered into force, titled "…to reclaim biodiversity, nature and the countryside." The law ratified the Nagoya Protocol, created the new biodiversity agency, and introduced an authorisation to access French genetic resources. The law states that financial benefit-sharing is calculated on the global turnover realised from the product derived from the genetic resource, capped at 5 percent. The access permit may be refused if the proposed benefit-sharing by the applicant "manifestly" does not correspond to its financial capacity. The new access legislation replaces the region-specific rules that already existed for the Amazonian Forest National Park in French Guyana.

Greenland and Denmark

Mainland Denmark does not have specific access requirements but does have user compliance rules. However, Greenland has its own government that does require a survey licence to access "biological resources" for research purposes. There is also an obligation to report patent applications resulting from the R&D to the government. Finally, a separate licence is required for the commercialisation of products and exploitation of the patent based on R&D on the biological resources.

Rules in User Countries

Rules in user countries are intended to ensure compliance with the rules in provider countries.

European Union

Since October 12, 2015, the EU requires companies conducting R&D ("users") to comply with the rules of the provider countries that are party to the Nagoya Protocol. To that end, EU rules require companies to track and trace the genetic resource from origin, through R&D, to final product. Companies must afterwards file a so-called "compliance declaration" before requesting a marketing authorisation (e.g., pharmaceuticals) or placing the product on the market (e.g., cosmetics, food). Finally, the EU requires that national authorities carry out audits of companies, and impose fines for non-compliance. So far, companies have reported the first audits taking place in the United Kingdom and the Netherlands.

France

France has provider-country rules as well as user-country rules, and the law contains sanctions to enforce both. Conducting R&D on genetic resources without having the required track-and-trace documentation is subject to one year imprisonment and a fine of up to 150,000 EUR. Conducting "commercial" R&D without the required documentation is subject to a fine of up to 1,000,000 EUR. For recipients of public research funding, infringement of the compliance obligations can result in having to repay the grant. Finally, if the R&D leads to a marketing authorisation, applicants must provide compliance documentation together with the main application. The authority granting the authorisation does not itself examine the documents, but must transmit them to the new biodiversity Agency. How this applies to EU bodies granting authorisations (e.g., European Medicines Agency) is currently unclear.

Germany

The German Law implementing the Nagoya Protocol and EU Regulation entered into force on July 1, 2016. The intentional or negligent violation of the compliance obligations is subject to an administrative fine up to 50,000 EUR. However, the limit is removed if the financial benefit obtained from the infringement exceeds that amount. The German Patent Act has also been amended. It now includes an obligation of the German Patent and Trademark Office to inform the Federal Agency for Nature Conservation in case a patent application relates to biological material. Although this would not block the granting of the IP right, it creates an additional "checkpoint" for compliance with the obligations under the Nagoya Protocol.

Switzerland

The Swiss Nagoya Ordinance entered into force on February 1, 2016. It contains compliance obligations that are very similar to the EU user compliance rules, although there are important technical differences. For example, a "user" is defined as the entity that conducts R&D on genetic resources, but also the entity that "directly derives advantages" from that R&D. Under the Swiss law, users must notify compliance to the Federal Office for the Environment (FOEN). When subsequently filing for an authorisation for, e.g., a medicinal product based on a micro-organism falling within the Nagoya Protocol, the applicant must communicate to the Swiss Medicines Agency (Swissmedic) that the Nagoya-related notification obligation applies, and provide the registration number received from the Federal Office for the Environment.

United States

The U.S. is not a party to the Convention on Biological Diversity, and hence also not to the Nagoya Protocol. That does not mean that U.S.-based companies are entirely free from the above-mentioned obligations. First, rules in provider countries will usually apply as a matter of national law. Second, U.S. companies may be captured by the compliance rules in user countries if they do R&D or business there. For example, even if a product has been researched and developed in the U.S., merely conducting a phase-three clinical trial in any of the 28 member states of the EU may be sufficient to trigger compliance obligations under the Nagoya Protocol.

Challenge for Industry

Upon reviewing their R&D pipelines, many companies are likely to find that the vast majority of their activities do not trigger provider country obligations. However, user countries' rules require that companies have in place processes to check *whether* access and benefit-sharing obligations apply. This necessarily implies reviewing all R&D activities. If the company then finds that Nagoya obligations *are* triggered, they must request public permits and negotiate benefit-sharing as required in the provider country.

Covington Team

Covington's global life science team has followed these developments since the negotiation of the Nagoya Protocol, working with a variety of sectors including pharmaceuticals, cosmetics, plant breeding and food. If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drug, and Device Practice Group:

Bart Van Vooren	EMEA	bvanvooren@cov.com
Peter Bogaert	EMEA	pbogaert@cov.com
Adem Koyuncu	Germany	akoyuncu@cov.com
Denise Esposito	United States	desposito@cov.com
Ruben Kraiem	Latin America	rkraiem@cov.com
Witney Schneidman	Africa	wschneidman@cov.com
John Balzano	Asia-Pacific	jbalzano@cov.com
Shaoyu Chen	Asia-Pacific	schen@cov.com
Anna Zhao	Asia-Pacific	azhao@cov.com