THE NAGOYA PROTOCOL AND THE MENTION OF GENETIC RESOURCES IN PATENT APPLICATIONS

The Nagoya Protocol regulates access to genetic resources and traditional knowledge; it sets forth general obligations for member States related to their use and the compliance of relevant measures for monitoring those obligations, as well as the fair and equitable sharing of the benefits arising from their utilization. The use of a genetic resource or traditional knowledge is defined by the Protocol as use in research and development for commercial or non-commercial purposes.

Some member States of the Protocol incorporated these obligations into their local legislation and others even developed them by adding specific features. States that are not members of the Protocol, although not bound by it in itself, may have their own legislation which may be similar to or different from the Protocol. In other words, the fact that a country of origin of a certain genetic resource or traditional knowledge is not a member of the Protocol does not mean that the user is exempt from obligations of a similar nature. In this regard, it is recommended that the users of any genetic resource and/or traditional knowledge verify whether the country of origin of those resources has local legislation that regulates access and use in order to comply with each country's requirements.

The European Union ratified the Protocol with Regulation 511/2014 and it's implementing Regulation 2015/1866. Both provisions are of direct application and they detail the measures of compliance of users of the Protocol on access to genetic resources and fair and equitable sharing of the benefits arising from their use in the European Union. It also sets forth that users should evidence due diligence and provide that information to the competent authorities through an internationally recognized certificate of compliance, containing the mutually agreed terms between the user and the regulatory body of the country responsible for that genetic resource.

However, neither of the two Regulations establishes the specific measures linked to the use of those resources in a patent application procedure, e.g. the obligation to submit that certificate of use to the Patent Offices if a genetic resource is used for developing a technology covered by a patent application.

Some Member States of the European Union incorporated this duty of information into their local legislation. Thus, to a greater or lesser extent, some countries within the European Union have regulated it in connection with patent application procedures. Countries such as France, Spain, Germany or the United Kingdom established obligations to inform the Patent Offices or the competent Biodiversity authorities (for example, in Germany the Federal Agency for the Conservation of Nature) about the origin of the genetic resources used to develop an invention covered by a patent application in the relevant country. This information may in some cases follow the general models provided for in Annex III of the Implementing Regulation 2015/1866 or such other models as local law may determine.

As an example, in Spain, the mention of measures related to patent applications was introduced through various legal texts:

- Law 42/2007, of 13 December, on Natural Heritage and Biodiversity (article 71): it sets forth a general provision in relation to patent applications related to genetic resources from wild taxa and it simply refers to current legislation on patents, with no further detail. The patent legislation in force at the time of the entry into force of Law 42/2007, was Law 11/1986 which didn't establish anything on the use of genetic resources and their mention in the patent application.

- Royal Decree 124/2017 of 24 February on access to genetic resources from wild taxa and control of use (article 14): it regulates how the users should carry out the due diligence in this matter. Particularly, in connection with patent applications, it provides that users must submit a declaration to the Ministry of Agriculture and Fisheries, Food and Environment **before** applying for a patent. The Spanish Patent Office shall verify compliance with the filing of that declaration in its patent application forms. Royal Decree 124/2017, however, expressly establishes that the obligation of information and due diligence declaration was not applicable until the date of entry into force of Law 24/2015, of 24 July, on Patents, i.e. April 1st, 2017.

- Law 24/2015 of 24 July on Patents (Article 23) and its Regulations (Article 2): it sets forth the obligation to include the information of the use of genetic resources in accordance with the provisions of the rules implementing the Protocol. Particularly, the registration number of the declaration of due diligence pursuant to Royal Decree 124/2017 shall be recorded at the Spanish Patent Office.

Thus, the applicability of the obligations of the Protocol at least with respect to users of genetic resources in the framework or with respect to a patent application procedure in Spain, derives mandatory as from April 1st, 2017. This is the reason for including a section on the patent application forms available at the Spanish Patent Office to **inform** about the use of genetic resources.

In the case of European patent applications however, there is nothing established as the European Patent Office *per se* is not affected by the European Regulations nor has the European Patent Convention (EPC) been modified due to the existence of the Nagoya Protocol and the obligations contained therein. Consequently, there are no regulations in the framework of the EPC that establish obligations similar or equivalent to those accepted by the European Union and/or the member countries of the Protocol.

On the other hand, the consequences of non-compliance with the information obligation were discussed by the Member States of the Protocol. Finally, the Protocol did not deal specifically with industrial property rights and, through its Article 15, left it to the Member States to define *"appropriate, effective and proportionate measures to deal with situations of non-compliance"*.

Several European countries do not establish specific consequences for non-compliance with the information duty, or what they do establish is that the declaration of due diligence in patent applications is not mandatory and does not affect the validity of the patent right.

In the case of Spain, it appears from Article 23 of Law 24/2015 that non-compliance does not affect the validity of the right. It seems clear, in our opinion, that Spain decided not to penalize with nullity or non-applicability of the patent and did decide to punish the infringement through the system of fines set forth in Law 42/2007. In Article 80 of Law 42/2007, non-compliance with the information obligation (which could include, inter alia, use in connection with a patent application) would be considered an administrative infringement with sanctions from EUR 3,001-200,000 (serious) to EUR 200,001-2,000,000 (very serious).

If non-compliance with the obligation to provide information does not affect the validity of the patent, it seems that a third party might activate the petition to the authorities to verify any infringement that leads the above-mentioned administrative sanctions are applicable. It remains to be seen if the lack of submission of the declaration within a patent application procedure falls into the non-compliance grounds in the authorities' eyes.

As mentioned above, Spanish patent law sets forth that the declaration of due diligence (the authorization of the use of the genetic resource) must be obtained **before** the filing of the Spanish patent application. In this regard, the Spanish Patent and Trademark Office has reserved a part on patent application forms to indicate the registration number or certificate number of legal access to the genetic resource. So far, the solutions for the different cases that may exist in practice are unknown since if the obligation of the user has a time limit ("before applying for the patent application") and the subsequent submission of this authorization is not foreseen, what remains to be resolved is the situations in which the user, having carried out all the procedures for obtaining the authorization in the relevant country, cannot obtain it before the date on which the user wishes or needs to apply for the patent.

In view of the above, when developing a technology by using genetic resources or traditional knowledge, it is advisable to follow a protocol of good practices and general compliance with the European and national legal provisions by including the verification of which legislation is applicable in each case; what type of research is carried out (with or without commercial purposes); what obligations have to be fulfilled according to the nature or origin of the genetic resource; which competent authorities and control points should authorize such use or with whom to negotiate mutually agreed terms for equitable benefit sharing; when or how far in advance the

due diligence statement should be obtained in time before applying for the patent; and if necessary, also declare the corresponding information in the patent application which, in the case of some countries such as Spain, is carried out on the same application form before the Patent Office.

In the case of European patent applications, while not affected by these obligations to inform the European Patent Office, the applicant of a European patent may also be obliged to comply with the requirements of the Protocol or the relevant European or local legislation for the use of a given genetic resource in the process of research and development of the technology claimed in that European patent application. Therefore, it is advisable to comply with homogeneous protocols regardless of the type of patent application that is finally filed to protect technology developed with the use of genetic resources or traditional knowledge.

Last but not least, it is advisable to also take into account these general principles on the use of genetic resources or traditional knowledge when negotiating and drafting technology transfer contracts (e.g. transfer of materials, know-how and/or patent licenses and/or assignments) in the event that the above obligations may or indeed do have an impact on the commitments of the parties to such agreements.

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