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Legal Update
December 2017

New Brazilian Law on Genetic Heritage gives one year to companies to report on their past activities having used Brazilian genetic heritage

The Brazilian National System of Management of Genetic Heritage and Associated Traditional Knowledge – referred to as "SisGen" – was launched online on November 6, 2017. This allows the full implementation of the Brazilian Access and Benefit Sharing ('ABS') legal framework introduced by the Federal Law No. 13,123 of 2015[1] ('Brazilian ABS Law').

From this date on, all companies – including global companies – that have accessed Brazilian genetic heritage, associated traditional knowledge, or that have commercially exploited final products or materials derived from these in the period ranging from 30 June 2000 until 17 November 2015 have one year to regularize their activities in accordance with the new law.

Brazil not being yet a party to the Nagoya Protocol on generic resources, this legislation creates an additional layer of ABS obligations for global companies conducting R&D and/or commercializing bio-based products. Companies are encouraged to set up a compliance strategy to conform their activities with the new Brazilian ABS Law. This should be part of the development a global strategy for compliance with ABS legislations, including the EU-ABS Regulation 511/2014.

The Brazilian ABS Law

The Brazilian ABS Law establishes the requirements that have to be observed by all companies (including outside of Brazil) which activities involve 'access' to Brazilian 'genetic heritage'. 'Access' means research or technological development conducted on a sample of genetic heritage or associated traditional knowledge. 'Genetic heritage' encompasses information of genetic origin from plant, animal or microorganisms, including metabolic substances. This covers Brazilian native species as well as some non-native species.

The conduct of activities classified as 'access' do not automatically trigger benefit sharing. Benefit sharing is only due when the access i) results in economic exploitation of a 'finished product' or of 'reproductive material' and ii) added significant value to said final product. A 'final product' does not require any additional production process and is ready to be used for final consumers. Adding significant value means that the accessed genetic heritage or associated traditional knowledge either determine the product's functional characteristics or its market appeal.

Declaration in SisGen

Access to genetic heritage can only be carried out **after** registration in an electronic system – SisGen. In cases involving access to genetic heritage in essential national security areas, as well as in maritime regions within Brazilian jurisdiction, prior government authorization is required. Electronic registration shall be carried out before samples are shipped abroad, as well as before commercialization. Importantly, foreign companies are only allowed to carry out R&D activities involving genetic heritage if in partnership with Brazilian institutions.

1 Law 13,123 of May 20, 2015, available in Portuguese on : http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Lei/L13123.htm. Subsequent related regulations are: Decree 8,772 of May 11, 2016, available in Portuguese on http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2016/decreto/D8772.htm; Decree 8,973 of January 24, 2017, available on http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2017/decreto/D8973.htm.

Before the commercialization of a final product, the manufacturer needs to notify SisGen and provide information on the applicant, final product or reproductive material, sector of application, as well as declare whether genetic heritage or associated traditional knowledge used in the final product determines the product's functional features or its market appeal. Information related to the scope (local, national, international) of manufacture and commercial distribution, relevant registrations already carried out, date of launch of the commercial distribution as well as the choice of the modality of benefit sharing mechanism (monetary or non-monetary) must also be provided. Information submitted to the system will be publicly available unless the user has expressly requested for confidentiality.

Regularization of Past Access

The publication SisGen also introduced a mechanism to regularise the situation for past access to genetic heritage. More specifically, all activities performed from the entering into force of the new law onwards (i.e. November 17, 2015) must be submitted to SisGen within one year.

Indeed, since November 6, 2017, all companies that have accessed Brazilian 'genetic heritage', 'associated traditional knowledge', or that have commercially exploited final products or materials derived from these in the period ranging from June 30, 2000 until November 17, 2015 have one year to either adequate and/or regularize their activities. Thus, the Brazilian ABS Law provides for obligations on companies that have i) carried out activities in accordance with the previously applicable Brazilian ABS legislation[2] ('Adequacy') and/or ii) infringed that previous ABS framework ('Regularization').

The Adequacy procedure applies to activities carried out in accordance with the previously applicable Brazilian ABS legislation[3] between June 30, 2000 and November 17, 2015. If the activities only involved access to genetic heritage or associated traditional knowledge, registration would be required. If the access led to economic exploitation of a final product or of a reproductive material, the new Brazilian ABS Law also requires benefit sharing for the economic exploitation carried out from 17 November 2015 onwards (except if benefit sharing was made in accordance with the previous Brazilian ABS legislation).

The obligation to regularize is applicable to companies that have carried out activities not in compliance with the previous Brazilian ABS legislation. Again, if access was limited to research activities, companies have the only obligation of registering at SisGen. However, if access resulted in commercialization of a final product or reproductive materials, a benefit sharing commitment covering all benefits realized from the moment the product or material was launched must be concluded. Such commitment extends to a maximum period of five years preceding the conclusion of the commitment and its conclusion suspends any sanction applicable for breach of the previous ABS legislation.

Benefit Sharing

Under the new Brazilian ABS Law, it is exclusively the manufacturer of the finished product or the producer of the reproductive material that is subject to benefit sharing obligations, regardless of whom has previously carried out the access. That company has the discretion to choose among monetary or non-monetary mechanisms of benefit sharing.

Monetary benefits are set at 1% of the annual net revenue obtained from the economic exploitation of the final product and, to ensure the competitiveness of a specific sector, they might be negotiated with the Brazilian Federal Union and be reduced to up to 0,1%. Even though this is not clear in the Brazilian ABS Law, it seems reasonable to infer that the annual net revenue is to be calculated worldwide. Non-monetary benefits should be equivalent to 75% of what would be owed in the monetary modality, and may *inter alia* include projects related to conservation or sustainable use of biodiversity or transfer of technology.

2 Medida Provisoria 2,186 of August 23, 2001, available on http://www.planalto.gov.br/ccivil_03/mpv/2186-16.htm

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Penalties

Administrative infringements of the Brazilian ABS Law, may be sanctioned by fines up to BRL 10,000,000 (approx. EUR 2,591,345). Moreover, depending on the seriousness of the fact, background and economic situation of the offender, and recidivism, sanctions may extend to (i) seizure of the samples, instruments or products derived from the access; (ii) temporary suspension of the manufacture and sale of the final product; (iii) embargo; (iv) partial or total prohibition of the establishment, activity or undertaking; (v) suspension or cancelation of the certificate or of the authorization.

Global Impact

All the obligations described above are applicable to any company sourcing or having sourced Brazilian heritage, whether based in Brazil, the EU, the US or elsewhere. With the launching of Sisgen and the countdown having started for the one-year deadline, every company should set up a compliance strategy with the Brazilian ABS Law.

Whereas the Brazilian ABS Law introduces ABS obligations on EU companies, Brazil is not yet a Party to the Nagoya Protocol. As a consequence, complying with the Brazilian ABS Law does not fall in the scope of the EU-ABS Regulation 511/2014[4], i.e. access to Brazilian resources does not trigger Due Diligence Obligations or a Due Diligence Declaration from EU companies. In any case, the Brazilian ABS Law provides for binding obligations, creating an additional layer of obligations for EU companies conducting R&D and/or commercializing bio-based products.

This is a very illustrative example of the current situation of ABS legislations at a global level, i.e. of the development of a lasagna of legislations at the international, national or regional level with very little coherence between one another and which often provide for broad and rather vague scopes of application.

Given its potential impact on global companies, compliance with the Brazilian ABS Regulation shall be encompassed within a global strategy for ABS legislations. Such strategy should include the development of internal guidance for departments in charge of the sourcing/purchasing of resources as well as those conducting R&D activities. A prerequisite is for the company to map its ABS obligations, depending on the configuration of its supply chain. It shall then develop interpretations of the legal texts in order to set up operative internal guidance. Legal support would certainly help in that respect.

If you have any questions or comments in relation to the above, please contact the authors or your usual Mayer Brown contact.

Thomas Delille
Associate, Brussels
E: tdelille@mayerbrown.com
T: +32 2 551 5958

Barbara Luvizotto
Associate, Brussels and São Paulo (T&C)
E: bluvizotto@mayerbrown.com
T: +32 2 5515965

or alternatively

Paulo Bessa
Partner, Rio de Janeiro (T&C)
E: pbessa@mayerbrown.com
T: +55 21 2127 4226

Solange Cunha
Associate, Rio de Janeiro (T&C)
E: scunha@mayerbrown.com
T: +55 21 2127 1630

Mayer Brown Europe-Brussels LLP and Mayer Brown Tauil and Chequer LLP

4 Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (OJ L 150, 20.5.2014, p. 59).

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