THE IMPACT OF THE NEW EU NAGOYA PROTOCOL COMPLIANCE REGIME ON THE COSMETICS INDUSTRY AS ILLUSTRATED BY *SOPHORA JAPONICA*

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Accusations of Biopiracy in the Cosmetics Sector

In 2013 an NGO published a paper on a cosmetics firm and its commercial interests in Asian medicinal plants.[1] Although it formulated no direct accusations or provide any evidence of piracy, the NGO thoroughly examined the product line of that company. In the paper it then determined that five Asian plant extracts were present in that company's cosmetics, and it linked these to publicly available information on patent claims. In the concluding part, the NGO then formulated rhetorical questions on where that company might have acquired these plants, and which benefit-sharing arrangements would be in place. In the cosmetics sector in particular, brands are at risk of such potentially damaging media campaigns. These debates often take place in a politically-charged North-South context, and this article will not enter that discussion. Rather, with the EU Nagoya compliance regime, the public relations risk is now also accompanied by a significantly increased legal risk. Therefore the goal of this article is purely to explain the EU Nagoya compliance regime by developing a hypothetical compliance scenario relevant to the cosmetics industry. The 'genetic resource' chosen for this article is *Sophora Japonica*, known in English as the Japanese pagoda tree or the Chinese scholar tree. We will also discuss a derivative from *Sophora Japonica*, the flavonoid *rutin* derived from its flower buds.

There has been extensive (ethno-)pharmacological and phytochemical research on *S.Japonica*.[2] As regards origin, academic literature by Chinese scholars states that it is native to China, and 'also found in Japan, Korea and Vietnam',[3] although the ILDIS database states that it is also native to Japan and Korea.[4] As regards ethno-pharmacology, *S.Japonica* was first listed 2000 years ago in a classic Chinese medical text as a medicine of the highest grade.[5] In Chinese traditional medicine it is used for hemostatic effects, and similar uses have been reported in Korean and Japanese traditional medicine. The *Sophora* flower and flower bud are both included in the Chinese Pharmacopeia, as well as the European Pharmacopeia. The flower bud contains a minimum of 15 per cent of *rutin*, making it a commercial source for the extraction of this flavonoid.[6] In cosmetics, *rutin* is mainly used for the purpose of hair conditioning and as an antioxidant in dermatological formulations.[7]

The ABC of the Nagoya Protocol

The 1992 Convention on Biological Diversity ('CBD') recognised that countries exercise sovereignty over the biological resources within their jurisdiction. This was the result of growing expectations of the commercial value of biodiversity, and the aim to undo the mismatch between

1) Third World Network, *Biopiracy Watch*, 2013, at 8 to 16.

2) Xirui He, 'Local and traditional uses, phytochemistry, and pharmacology of Sophora japonica L.: A review' *Journal of Ethnopharmacology* (forthcoming).

3) *Ibid.*, 2.1. Botany.

4) http://ildis.org/cgi-bin/Araneus.pl (accessed 2 May 2016).

5) See Note 2 above, 2.2. ethnopharmacology.

6) Council of Europe, *Plants used in cosmetics*, Volume III: potentially harmful components, 2006, pages 221 to 225 (*rutin*).

7) *Ibid.*

mostly developing nations' rich biodiversity, but lack of capacity to research and develop these genetic resources into commercial products. The 2010 Nagoya Protocol thus aims to ensure that the financial and non-financial benefits arising out of R&D conducted on genetic resources will be 'fairly and equitably shared'[8] with the country of origin. To achieve this goal, this international agreement consists of three clusters of rules, the so-called 'ABC' of the Nagoya Protocol.

Access Rules

Since parties exercise sovereignty over their resources, the Nagoya Protocol allows parties to require a public permit to acquire a genetic resource and/or related local traditional knowledge. This is known as 'prior informed consent' ('PIC'). In the *S.Japonica* example, PIC means that prior to acquiring the plant (and related traditional knowledge on its health-related properties), one should check whether public authorisation is required, and comply as appropriate. Establishing which Nagoya party should give permission for access can be challenging, as it requires establishing the country of origin of *S.Japonica*.[9] As stated, Chinese literature seems to claim that it is native only to China, although Korea and Japan stake similar claims. Korea and Japan have signed the Nagoya Protocol but must still ratify it, and China has not signed or ratified. Assuming that Korea and Japan become parties, these competing claims can be highly problematic under the EU Nagoya compliance regime.[10] Finally, the EU and six EU Member States are also parties to the Protocol, and more EU Member States are about to join.[11] While the United States is not a party, that does not mean that American companies remain unaffected by the Nagoya Protocol, especially when they are active in the EU.

Benefit-sharing Rules

Aside from PIC, Nagoya parties may require that the entity seeking to acquire genetic resources and related traditional knowledge concludes a contract with local partners on how benefits from R&D on the genetic resources will be shared. This is referred to as 'mutually agreed terms' (or MAT) and the Annex of the Nagoya Protocol provides examples of non-financial and financial benefits. In our example, monetary benefits from R&D on *S.Japonica* could include milestone payments, licence fees in case of commercialisation, joint ownership of resulting patents, or making the resulting product locally available at a preferential price. Non-monetary benefits can include providing education and training to local researchers, providing access to scientific results of the R&D, or supporting build-up of local technological and material capacities. Under Nagoya, benefit-sharing can be attached to the genetic resource or related traditional knowledge as two distinct categories (albeit in the same MAT). Thus, monetary benefits can relate to R&D on the genetic resource *S.Japonica* itself. Benefit-sharing can also be attached to R&D resulting from Chinese, Japanese or Korean traditional medicinal knowledge on its hemostatic or anti-oxidant properties, and flow back to the (indigenous) community holding the (oral) tradition.

Compliance with Access and Benefit-sharing Rules

Parties to the Nagoya Protocol are not obliged to adopt PIC and MAT obligations. For example, India has reported such rules to the ABS clearing house, whereas the Democratic Republic of Congo has not. However, the Protocol does require that all parties adopt enforcement rules to ensure that R&D within their own jurisdiction is compliant with applicable access and benefit-sharing legislation of the countries of origin of the genetic resources that are Nagoya parties.

The implementation of this 'ABC' of the Protocol within the EU is divided between the national and Union level. The Member States are competent to adopt rules on access and benefit-sharing ('AB') since they have sovereignty over their genetic resources. The EU has adopted the compliance rules across the entire EU internal market ('C'), but civil and criminal sanctions and enforcement procedures are again adopted at the Member State level.

8) Article 5, Nagoya Protocol to the Convention on Biological Diversity.

9) Article 2 of the Convention on Biological Diversity defines the country of origin as that which 'possesses those genetic resources in *in-situ* conditions'.

10) Article 3(8) of the Basic Regulation states that 'illegally accessed genetic resources' are those which were not accessed in accordance with the national legislation of the *provider country* that is a party to the Nagoya Protocol requiring prior informed consent. This is at odds with Article 5(1) of the Nagoya Protocol itself, that refers to the 'party providing such resources that is the country of origin of such resources'.

11) Germany ratified the protocol in April 2016, and Belgium is in the process of ratifying.

The EU compliance regime consists of two legal instruments: first, Regulation 511/2014 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' ('the Basic Regulation').[12] This Basic Regulation has been supplemented with an Implementing Regulation of 13 October 2015 with, among other aspects, rules on how compliance will be monitored by national authorities ('the Implementing Nagoya Compliance Regulation').[13] Between 2016 and 2017, the Commission will also publish several sector-specific 'guidance documents' to give guidance to pharmaceutical companies, plant breeders, chemicals companies, and others, on how to comply with the new regime. On 27 August 2016, the general guidance document was published.[14]

Establishing Whether the Company Falls under the EU Rules

The scope of the Basic Regulation is defined in sweeping terms. Companies and universities may both be captured by the EU rules when they conduct R&D on 'any material of plant, animal, microbial or other origin containing functional units of heredity'. This could include honeybush, microbes, aloe vera, pineapples, lavender, cows, lemongrass and so on. The Nagoya regime also intends to include derivatives such as, for example, enzymes derived from pineapple, lipids, flavonoids, proteins or flower fragrances. Commercial and non-commercial entities conducting R&D on these genetic resources are called 'users'. As a first step, such users will need to know whether their activities are *at all* covered by the EU's Basic Nagoya Regulation. In what follows, we provide a brief example of how to conduct that exercise.

Unfortunately, there is significant legal uncertainty, mainly because the EU rules were adopted without sufficient attention being given to the diverse sectoral R&D processes they regulate. We briefly highlight a few basic conditions for the regime to apply, continuing our example of *S.Japonica* and the derivative *rutin*. The hypothetical summary is not comprehensive and the following conditions are cumulative.

- First, any natural or legal person who conducts R&D on genetic resources and traditional knowledge within the EU, is subject to the Basic Nagoya Regulation. The location of R&D within one of the 28 EU Member States is the geographic anchor-point. This means that if a US-owned cosmetics company conducts R&D on *S.Japonica* in a research facility in an EU Member State, it would be captured by the compliance obligations in the Regulation. Conversely, R&D entirely outside the EU, even when the resulting product is ultimately marketed within the EU, would not be captured by the compliance regime.

- Second, the Regulation applies to genetic resources and traditional knowledge accessed after 12 October 2014. This is the day on which the Nagoya Protocol entered into force for the EU.[15] If the cosmetics company conducts R&D on *S.Japonica* flower buds acquired after that day, the EU Regulation would apply. Conversely, if the flower buds were acquired before that date, dried and held in storage by that company, the R&D activities after 12 October 2014 would in principle fall outside the EU compliance regime.

- Third, the acquisition of the genetic resource and related traditional knowledge must have occurred in a party to the Nagoya Protocol. As mentioned, there seems to be some dispute in the literature whether *S.Japonica* is native only to China, or also to Japan and Korea. Upon ratification the latter two countries will become parties to the Nagoya Protocol, but China has not signed. Although all three countries may have PIC/MAT requirements, once Japan and Korea ratify, only acquisitions of *S.Japonica* from these countries would trigger the application of the EU compliance

12) Regulation (EU) No 511/2014 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 20 May 2014, L150/59–71.

13) Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices, OJ 20 October 2015, L275/4–19.

14) European Commission Guidance document on the scope of application and core obligations of Regulation 511/2014, OJ 27 August 2016, C313/1.

15) Notice concerning the entry into force of the Nagoya Protocol, OJ 27 September 2014 L283/1.

regime. This may lead to *forum shopping* in acquiring the genetic resource: access in China would mean no compliance obligations under the EU regime, but could imply the application of strict Chinese access rules such as the obligation to return the sample of the genetic resources to China. Alternatively, a company may choose to acquire *S.Japonica* in Japan and Korea if the access regime is easier to comply with. In that case, subsequent obligations under the EU regime may not present a significant obstacle either.

- Fourth, the Nagoya Protocol applies to genetic resources, but also to 'traditional knowledge associated with genetic resources'. This is 'knowledge held by an indigenous or local community which is relevant' for the R&D.[16] Chinese researchers have reported that *S.Japonica* was already listed in the classic Chinese medical text 'Shen-Nung's Pen-Ts'ao' 2000 years ago in the Han Dynasty,[17] and their ethno-pharmacological research shows the various applications of *S.Japonica* as it emerged from traditional knowledge from China, Korea and Japan. Suppose that this leads researchers of a commercial cosmetics producer to conduct further R&D that eventually leads to the commercialisation of a skin conditioner, the EU Nagoya compliance regime applies and requires that any applicable access and benefit-sharing rules linked to the genetic resources or the traditional knowledge are complied with.

- Fifth, the Nagoya Protocol and the EU compliance regime apply to genetic material that is defined as 'any material of plant, animal, microbial or other origin containing functional units of heredity'. Parts taken from the *S.Japonica* tree such as flower buds fall within that definition. However, *rutin* as a flavonoid derived from these flower buds, itself does not contain 'functional units of heredity' of *S.Japonica*. Therefore, R&D on *rutin* or other derivatives common to the cosmetics sector such as essential oils, lipids or fragrances, should not fall within the EU Nagoya compliance regime. However, the EU regime states that utilisation of genetic resources includes R&D on their 'biochemical composition'. The drafting history of the Nagoya Protocol suggests that this must be interpreted to include derivatives that are products of cellular metabolism.

- Sixth, and finally, 'research and development' is a commonly used expression, but it is not defined in the EU Regulation. Depending on the specific activity carried out on *Nigella S.Japonica* or *rutin*, this can raise questions as to whether the EU regime applies. For example, is it R&D to merely extract *rutin* from the flower buds acquired from China? Is growing and breeding *S.Japonica* research and development? If not, will the EU regime only apply if the cosmetics company also selects Pagoda tree varieties with greater *rutin* content? Is receiving purely digital information on *rutin* from Chinese trees considered to constitute 'acquisition' of a genetic resource, and would *in silico* research to synthesise the compound be covered? In the general guidance document of 27 August 2016,[18] the Commission intends to provide clarification. The guideline states that users should assess whether the R&D 'creates new insight' into the genetic and/or biochemical characteristics of the resource. Commodity trade in *S.Japonica* plants would thus not be captured, but most other activities would easily fall within that definition. Finally, basic research without the intention to develop a product will likely also be captured by the EU compliance rules. For example, university researchers that solely investigate whether traditional knowledge on the health effects of *S.Japonica* can be experimentally proven. Views on this point do diverge, since, for example, provider countries argue that pure development should also be covered.

The Obligations under the EU Rules

Once the company has established that the EU Regulation applies to its activities, it imposes an obligation 'to exercise due diligence'[19] to ascertain that users conduct R&D in accordance with PIC and MAT obligations. The reference to due diligence can be misleading, because the failure to comply can result in strict sanctions. This includes the obligation to discontinue R&D on the genetic resource, and an impact on the commercialisation of the resulting product cannot be excluded. The EU Regulation also includes a whistle-blower system, whereby Member State enforcement authorities are obliged to take special account of information received from third countries that are parties to the Nagoya Protocol.

16) The full definition can be found in Article 3(7) of the Basic Nagoya Compliance Regulation.

17) See Note 2 above, 2.2. Ethnopharmacology.

18) Note 14 above.

19) Basic Nagoya Compliance Regulation Article 4(1).

To comply with the due diligence obligation, users must 'seek, keep and transfer to subsequent users'[20] information and documentation on the genetic resources on which they conduct R&D. This is essentially a 'track and trace' obligation, which means that users must:

- First, exercise a sufficient level of care and effort so as to (a) know whether the Nagoya Party has access (PIC) and benefit-sharing (MAT) rules, (b) ensure that prior informed consent is obtained where necessary, and (c) negotiate mutually agreed terms if required. Assume that Japan has already ratified the Nagoya Protocol. In the case of acquiring *S.Japonica* from that country, the first step would be to consult the 'Access and Benefit-Sharing Clearing House'.[21] This is an online platform where all parties to the Nagoya Protocol should upload their applicable legislation, as well contact information for a National Focal Point to guide the researcher in getting PIC and negotiating MAT. However, the platform does not provide legal certainty that there is national legislation. Under the EU compliance regime, evidence of simply accessing the online platform does not suffice to comply with the due diligence obligation.

- Second, set up a database containing the information and documentation previously obtained. Was the *S.Japonica* accessed in Japan or China, and at what time? If in Japan, did access and benefit-sharing legislation apply? If required, was PIC obtained, and was MAT negotiated? Have we shared benefits as legally required under the MAT, and if so, which, when and how? This information must cover the entire time-period of the R&D, and the user is obliged to keep this data for 20 years after the R&D ends.[22]

- Third, under the EU Compliance Regulation, provide this documentation and information to subsequent users to ensure a 'chain of compliance' from one user to the next. Issues of commercial confidentiality under this obligation have not been addressed in the EU Regulation.

Thereafter, the user conducting R&D must also make a 'compliance declaration' at two moments.[23] This will allow national competent authorities to monitor user compliance under the Nagoya Protocol. A central EU web-portal is being developed where users will have to upload their compliance declarations. The moments for the declarations are:[24]

- When a public or private grant is received to carry out R&D on the genetic resource or associated traditional knowledge; and

- At the stage of final development of a product developed through R&D on the genetic resource or associated traditional knowledge.

The second checkpoint is likely the most significant. Prior to seeking market approval, placing the product on the market, or even selling the result of R&D outside the Union, the user must declare and prove compliance with the EU obligations under the Nagoya Protocol. Parts of the declarations will be publicly accessible. For example, although not an EU Member State, Switzerland is a member state to the Nagoya Protocol. Article 11 of the Swiss Nagoya implementation law[25] expressly states that, for cosmetic products, the *Office fédéral de l' environnement* (OFEV) will be competent to check whether for products derived from genetic resources and related traditional knowledge the Nagoya obligations have been complied with.

Similar laws are being adopted within the Union, since the EU Regulation requires that its compliance obligations are supported by national civil and criminal enforcement rules in all Member States. For instance, in the United Kingdom, the National Measurement & Regulation Office (NMRO) has been appointed as the national competent authority. It acts in accordance with the Nagoya Protocol (Compliance) Regulations 2015. The rules foresee civil sanctions for failure to exercise due diligence, failure to track and trace information, and failure to make the declaration. Civil sanctions include compliance notices, variable monetary penalties, and also stop notices on the commercialisation of products where PIC and MAT have not been complied with. Failure to comply with civil sanctions is subject to criminal sanctions.

20) *Ibid.*, Article 4(3).

21) Available at: https://absch.cbd.int/.

22) Basic Nagoya Compliance Regulation Article 4(6).

23) *Ibid.*, Article 7.

24) Implementing Nagoya Compliance Regulation Articles 5 and 6.

25) Ordonnance sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation (Ordonnance de Nagoya, ONag) du 11 décembre 2015: https://www.admin.ch/opc/fr/official-compilation/2016/277.pdf.

Conclusion

The EU compliance regime is still in its infancy and many aspects require clarification. The European Commission published on 27 August 2016 a general guidance document clarifying the scope of application of EU rules. The Commission will subsequently work on sector-specific guidance documents covering cosmetics, food and beverages, pharmaceuticals, plant breeding, biocides, and other relevant sectors. These documents will focus on sector-specific R&D processes on genetic resources, and should be finalised in 2017. Trade associations based in Brussels are actively engaged in this drafting process, but individual companies are strongly advised to monitor and participate when needed. Similarly, it is crucial to monitor developments at national level. For example, the new French biodiversity law linked to the Nagoya Protocol was adopted at the end of July 2016. The newly founded French Biodiversity Agency is expected to become operational on 1 January 2017.

Although the Nagoya legal regime is still a moving target, in order to avoid problems with commercialisation in a few years' time, it is important that companies already now put in place procedures that implement, adequately document and declare due diligence. These procedures can then be updated when guidance documents of the Commission are available, and in line with national enforcement practice by Member State authorities. It is also likely that the EU Court of Justice will ultimately have to interpret specific aspects of the regime.