Chapter 17

Disentangling Due Diligence – Making sense of the EU Regulation 511/2014 transposing the Nagoya Protocol

Christine Godt & Markus Burchardi

1 Due Diligence

The European Union transposed the CBD-Nagoya Protocol of 2010 by way of Regulation (EU) No. 511/2014.¹ It rests on the so called 'due diligence' concept. The central norm Art. 4.1 Reg. 511/2014 stipulates:

"Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilize have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements."

Its rationale is that the EU does not directly apply and enforce provider states' measures.² A direct enforcement of provider states' norms would, so the argument goes, violate the territoriality principle.³ Instead, it installs a 'duty to comply' as a sui generis duty under EU law. Yet, what does this mean? What needs to be done to 'exercise due diligence'? What is the standard of care? Who decides what is necessary and sufficient, especially in the light of Art. 4.5 Reg. 511/2014, which reads:

"When the information in their possession is insufficient or uncertainties about the legality of access and utilisation persist, users shall obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation."

2 Different roots and common ground

The due diligence duty came about as a compromise formula which attracted the approval of many stakeholders. It became acceptable to various political camps, industry and non-governmental organisations alike. This was possible because the term 'due diligence' has different connotations for different audiences. For international public lawyers, the term resonates with a long-lasting debate about state liability. For European lawyers, the term has become fashionable in the emerging field of corporate social responsibility (CSR) Regulations in various sectors. Corporate lawyers associate 'due diligence' with the established

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, 59–71.

² On this earlier idea of how 'user measures' are to be installed: Barber, C. S., Johnson, S., Tobin, B. (2003).

³ This principle is conceptualised as fundamental to public law. In contrast, private international law is based on comity and regulates via a set of rules ('conflict of law rules') stipulating under which conditions and to which extent a national judge will apply foreign law, see Kegel, G., Schurig, K. (2004), at pp. 135 et seq.

COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT (2012), at pp. 44, 51; ICC Document "Nagoya Protocol Implementation in the EU".

⁵ E.g. ILA Study Group on Due Diligence First Report (2014), at pp. 2 et seq. See also Kulesza, J. (2016), at pp. 3, 115 et seq.

⁶ Council Regulation (EC) No 2368/2002 of 20 December 2002 implementing the Kimberley Process certification scheme for the international trade in rough diamonds, OJ L 358, 31.12.2002, p.28; Regulation (EU) No

business practice to thoroughly check documentation prior to a transaction, which rests on specific liability rules in International sales law. Thus, while a single term found its way into the Regulation, it is not at all clear what the specific content of due diligence is in the concrete context of the new Regulation 511/2014. The problem of compromise is amplified by the background of the discussion surrounding legal transplants. While some authors conceive the adoption of new legal concepts as the central driver of socio-legal progress, system theory scholars maintain that a legal system cannot 'adopt' a concept. At best, new concepts 'irritate'. Put pointedly, the counter position follows the argument that it is not the transplant, which changes the law, but inversely, it is the surrounding law – in this case EU law – which will change the transplant.

The common ground of the various ideas of the political stakeholders appears to be the notion of due diligence as industrial self-governance. Our ongoing component project to the DFG-project directed by Evanson Kamau looks more profoundly into the various concepts, which were amalgamated in Art. 4.1 Reg. 511/2014. It looks into the adjudication of due diligence by international arbitral courts and tribunals, into the adjudication of the Internal Court of Justice as regards state liability, and, in more depth, into various EU Regulations.

3 A unique European quality sui generis

We scrutinized several EU Regulations⁸ that can be identified as 'due diligence regimes'. While sharing certain structural elements, these regimes still differ in their overall architecture and (self-) regulatory thrust. Yet, together they form the background and make up today's legal environment in which Art. 4.1 Reg. 511/2014 is to be interpreted as autonomous EU law sui generis. The central question thus becomes: What exactly constituted the (European) compromise? What is due and who decides in case of a dispute between authorities and industry?

In our research, we identify 'EU due diligence' as a distinct instrument with a unique function, which draws on three distinct normative legacies stemming from public international law, international business law and EU law. Its function is that of a hinge joint: Provider states' laws are not applied as such, but Art. 4.1 Reg. 511/2014 rather 'translates' the 'prohibition' under foreign law into a domestic duty to only utilize 'legally acquired material'. The norm has the function of a (classical) conflict of laws rule. Art. 4.1 Reg. 511/2014 'opens the door' for the application of foreign law and proceduralises its enforcement. Insofar as it does not pre-define the substance/the result/the outcome of said application, and thus only

995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market OJ L 295, 12.11.2010, p. 23–34; Regulation (EU) 2017/821 of the European Parliament and of the Council of 17 May 2017 laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and highrisk areas, OJ L 130, 19.5.2017, p. 1–20.

⁷ Due diligence in the corporate world can be equated with the defence requirement in Arts. 38-40 United Nations Convention for the International Sale of Goods (UN CISG) to 'give timely notice'. Regarding the structure of the various types of due diligence in the process of acquiring a company or its assets, see Bainbridge, S.M., Anabtawi, I. (2017), at pp. 255 – 263.

Apart from the 'supply chain' Regulations already mentioned under fn. 6 supra, we scrutinized Regulation (EU) 2015/757 of the European Parliament and of the Council of 29 April 2015 on the monitoring, reporting and verification of carbon dioxide emissions from maritime transport, and amending Directive 2009/16/EC OJ L 123, 19.5.2015, p. 55–76; Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, 4.5.2016, p. 1–88; Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1–175.

provides for a normative yardstick to evaluate user behaviour, we see the influence of the preceding debate on due diligence in public international law. In this sense, Art. 4.5 Reg. 511/2014 provides for time and leeway for communication between the regulator and the user. As such, it installs a vertical (user country sui generis) 'duty to produce (diagonal) compliance'. The user may take efforts to re-negotiate PIC and MAT with foreign agencies. In case of problems, he/she may consult with domestic agencies. The duty to produce compliance finds its limits in the real world, where agencies in other countries do not respond or have fallen apart for political reasons. These considerations are to be taken into account; a nuanced decision can be taken by the responsible user state agency.

In the business world, due diligence denotes the practice of conducting ex ante inquiries into a target company or its assets prior to a takeover. Here, the objective standard of corporate liability prescribes 'what ought to be done, needs to be done'. The subjective standard of 'what ought to be known' is determined ex post. Proving that all reasonable investigative efforts (to identify non-hidden defects) were exhausted can be a valuable defence, thus forcing the buyer to install an appropriate risk-management system. This is the corporate law legacy of EU due diligence.

In addition, EU due diligence sees an added layer of regulatory legacy stemming from the Community's own regulatory environment that the concept of due diligence was transplanted into. Said legacy relates to notions of industrial self-governance, orchestration by the state, the consequences of using regulatory intermediaries (or lack thereof), and here in particular the peculiar role of (registered) collections.

Combining those three legacies mentioned above, we developed five qualifications of the sui generis due diligence duty under Art. 4 Reg. 511/2014:

- First, the duty to discontinue in Art. 4.5 last sentence Reg. 511/2014 is a substantive (not a procedural) obligation, which implies that the time window for efforts to remedy an incompliant situation is not open ended and is not at the discretion of industry.
- Second, there is no shift of responsibilities. Due to a lack of industrial engagement in norm-building and enforcement, a 'risk absorber' for industry is non-existent. These elements translate into a strong role for national competent authorities (NCAs).
- Third, the subjective standard of care ('what ought to be known'), in particular the exact terms of risk evaluation and risk management, depends on the professional standard of the respective industrial sector.
- Fourth, a firm's individual capacities (e.g. experience, time or money) are not seen as valuable defences regarding the procedural duties.
- Fifth, the Regulation creates a double (non-identical) duty as regards the objective standard of care ('what ought to be done'). The duty to comply under foreign law is complemented by a domestic duty to only use legal material. These duties are intertwined. The restricted scope of the EU-Regulation (e.g. material accessed on the territory of a NP-signatory) reduces the pressure of compliance. On the other hand, it creates administrative burden where provider states do not regulate. In turn, the domestic duty may ease the regulatory burden where PIC is not available, but a discontinuation of utilisation would be un-proportional.

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Figure 5: Project team outside the Forschungsstelle fuer Europaeisches Umweltrecht (FEU), University of Bremen (27 June 2019). Front row from left: EC Kamau, JC Medaglia, MV Cabrera Ormaza, M Burchardi, G Burton, E Beck, C Williams, CDT Nguyen, AY Cho. Back row from left: MT Mahop, CHC Lyal, G Winter, T Greiber, Y Ha.



Figure 6: Project team at the entrance to the University of Bremen "Glass Building" (28 June 2019). First row from left: MV Cabrera Ormaza, Y Ha, AY Cho. Second row from left: M Burchardi, G Burton, JC Medaglia, CDT Nguyen. Third row from left: LM Mozini, C Godt, C Williams, G Winter. Fourth row from left: CHC Lyal, MT Mahop, EC Kamau, T Greiber.