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The Nagoya Protocol on ABS: ratification by the EU and its Member States and implementation challenges

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ABSTRACT

The paper contains a survey of the background and the content of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization in respect to which the EU Council has committed itself to a timely ratification and effective implementation. The paper also considers some questions of interpretation arising from the Protocol including particular references to a report of the EU Commission on the outcome of the final negotiations in October 2010 on the Protocol. Some findings of the Commission are questioned. Key messages are, *inter alia*, that it is doubtful, as claimed by the EU Commission, that unilateral ratifications by Member States would be in conflict with the EU Treaty, and that decisions made by the Conference of the Parties of the Convention on Biodiversity serving as the first meeting of the Parties of the Protocol might make it impossible for the EU to ratify the Protocol. It is argued that late ratification of the Protocol by the EU would send a rather negative signal to developing countries. On the other hand, common rules in various respects on the EU level might have some positive implications. The Protocol presupposes an explicit decision by EU Member States on whether and to what extent to apply the principle of prior informed consent (PIC) for access to genetic resources. Ultimately, such a decision implies a political choice which, however, has to be based on advice of e.g. the scientific community. With Danish legislation as an example, the paper is analyzing some aspects to be considered. An analysis of the present legal status of genetic resources is needed, in particular *vis-à-vis* property rights over biological resources, since PIC can hardly be a stand-alone requirement. Although EU member countries have hitherto mostly regarded themselves as user countries, the time has now come to consider in a detailed manner their roles also as potential provider countries and to make the necessary decisions in that respect.

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Translations of Greenland and Norwegian legal texts quoted in the article are referred to by the relevant Greenland and Norwegian authorities providing the texts as unofficial translations. Translations of Danish legal texts were made as part of the translation of the original article in English, thus being unofficial translations. The author wishes to thank Søren Mark Jensen, Danish Nature Agency, for his help in clarifying relevant scientific issues and Claudio Chiarolla for suggestions and comments on the original article. However, the responsibility for any mistakes or errors remains with the author. The author also wishes to thank participants in the First Review Workshop on the IUCN Draft Guide to the Nagoya Protocol on Access and Benefit-Sharing, 8-9 December 2011 at the IUCN Environmental Law Centre in Bonn, Germany, in which the author participated as an advisor. Although discussions at the workshop only and specifically related to the Draft Guide, they may indirectly have had an impact as a source of inspiration on some aspects of the present article. Unless otherwise stated, opinions expressed in the article remain, of course, those of the author.

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TABLE OF ACRONYMS

ABS	Access and benefit-sharing
Bird Conservation Directive	DIRECTIVE 2009/147/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on the conservation of wild birds
Bonn Guidelines	Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization
CBD	Convention on Biological Diversity
COP	Conference of the Parties
COP-MOP	Conference of the Parties serving as the Meeting of the Parties to the Protocol
FAO	Food and Agriculture Organization of the United Nations
FAO Treaty	International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
Habitat Directive	COUNCIL DIRECTIVE 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora
ICG	Intergovernmental Committee (under the COP of CBD or under the General Assembly of WIPO pending the context)
ILC	Indigenous and local communities
IPR	Intellectual property rights
MAT	Mutually agreed terms
PIC	Prior informed consent
PIP	Pandemic Influenza Preparedness
Protocol (or Nagoya Protocol)	Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biodiversity
TK	Traditional knowledge
TRIPs	WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCLOS	United Nations Convention on the Law of the Sea
UNDRIP	UN Declaration on the Rights of Indigenous Peoples
UPOV	International Convention for the Protection of New Varieties of Plants
VLTT	Vienna Convention on the Law of Treaties
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1. INTRODUCTION

On 29 October 2010, the tenth meeting of the Conference of the Parties (COP 10) to the Convention on Biological Diversity (CBD)[1], in Nagoya, Japan, adopted the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* (the Nagoya Protocol or simply the Protocol).[2] The Protocol contains a series of commitments in relation to access to genetic resources for both the countries in which the resources are located and for recipient countries, and corresponding commitments concerning the equitable distribution of the benefits arising from the utilization of genetic resources (i.e. benefit-sharing). On 20 December 2010, the Council of the European Union committed itself to a "timely ratification and effective implementation" of the Protocol and invited Member States to sign the Protocol at the earliest opportunity and to begin the preparation of a timely ratification and implementation.[3]

Against the backdrop of the EU Council decision to adopt the Nagoya Protocol, the three objectives of this paper are to: introduce the background of the Protocol; review its content and consider some of key legal and policy questions in light of the Protocol's forthcoming implementation; and assess its relationship with the Danish legislation with the view to draw some key lessons learned for implementing the Protocol at the EU level. This introduction explains the concept of genetic resources and the practical importance of the Protocol for regulating the commercial and non-commercial use of biodiversity-based research outcomes. Section 2 provides a review of key relevant CBD provisions. Section 3 describes the developments leading up the adoption of the Nagoya Protocol in Nagoya. Section 4 addresses some problems stemming from the concepts of utilization of genetic resources and utilization of traditional knowledge of indigenous and local communities. Section 5 summarises the Protocol's content, while section 6, focusing in particular on an assessment by the EU Commission, considers its scope of application and the associated legal problems. Section 7 discusses the Protocol's relationship with Danish legislation, using Norwegian legislation as a source of inspiration, with the view to draw key lessons learned for implementing the Protocol at the EU level. Finally, section 8 concludes by arguing that most challenges of the Protocol, in spite of a number of interpretative issues, are related to the requirements of the Protocol concerning domestic legislation. As far as the EU is concerned, it is questioned whether unilateral ratification of the Protocol by Member States would be in conflict with the EU Treaty as claimed by the Commission. It is, furthermore, argued that late ratification, presupposed by the Commission, would send a rather negative signal to developing countries. Admittedly, however, some common or uniform rules within the EU might be advantageous in various respects. Since Member States, also *vis-à-vis* the EU as such, have sovereign rights over their natural resources, they should, in any event, commence analyzing the present legal status of their genetic resources right away with a view of deciding whether (and to what extent) to implement their right to require PIC.

The primary subject matter of the Nagoya Protocol is genetic resources since it is access to such resources and the sharing of the benefits arising from their utilization that the Protocol intends to regulate. Therefore, examining the meaning of the concept of genetic resource is important for understanding the Nagoya Protocol.

1. The Convention has been adopted by almost all states, with a total 193 Parties including the European Union. A noticeable exception is the United States, which as a non-Party to the CBD cannot become a Party to the Nagoya Protocol, cf. Article 33(1) of the Protocol.
2. The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*, can be accessed on the Convention's homepage at: http://www.cbd.int/. The decisions of the Conferences of the Parties to CBD referred to in the following footnotes can also be accessed on the CBD website.
3. *Conclusions of the Council of the 20th of December 2010* (CL10-144EN) on the result and follow-up of the Nagoya-Conference (from 11-29 October 2010), at section 14 and 21. The Protocol opened for signature from 2 February 2011 to 1 February 2012.

As the term indicates, a genetic resource is a biological material, i.e. something stemming from plants, animals, fungi or micro-organisms which may be considered as the first condition. Not all biological material is covered. This is because a second condition is that the genetic resource must contain functional units of heredity, i.e. genes (DNA) that can pass on properties to the next generation. Therefore, a genetic resource, in the sense that is specified by the CBD, is not simply biological material, but also genetic material. The whole of a plant or a leaf are genetic materials whereas a bag of flour, a cotton t-shirt or a leather jacket are made of biological materials but they are not genetic material, because they no longer contain functional units of heredity. A single gene inserted into another organism to transfer a specific property to the organism (e.g. to make it resistant to a specific pesticide) is also genetic material. Such a gene has an actual or potential value and it may satisfy the third condition necessary for a material to qualify as a genetic resource, which is that it has an actual or potential value[4]. A fruit to be eaten is made of genetic material because it contains functional units of heredity. It is, however, eaten for its nutritional properties and physical composition and not due to the functional units of heredity. Hence, it may be argued that a fruit or other biological resources only are becoming genetic resources if and when the value of their genetic resources and/or biochemical makeup are being realized or projected to be utilized, such as in crop improvement, crossing or propagation in plant breeding or as basis for production of organic substances, including medicinal substances, vitamins or enzymes. In any event, the Protocol is only relevant to genetic resources being utilized in the sense of the Protocol[5] as well as subsequent applications and commercialization[6].

However, the concept of genetic resources is also used in other international instruments, but not necessarily in the same way.[7]

Genetic resources are of great importance, *inter alia*, for food, cosmetics and pharmaceutical industries. Hence, an international instrument such as the Nagoya Protocol, which regulates access to genetic resources and contains provisions on the sharing of benefits arising from their utilization, has significant practical implications for both commercial and non-commercial research. In particular, from a national perspective Denmark, as well as most other European countries, has an economically important biotechnological and pharmaceutical industry, while being a potential provider of genetic resources.

About the same time as the adoption of the Protocol a book titled "Norsk Genressursrett" (Norwegian Genetic Resource Law) by Morten Walløe Tvedt was published. The book does not discuss the Nagoya Protocol as such and it provides for a broader approach to ABS issues in terms of its subject matter.[8]

2. THE CBD PROVISIONS ON ACCESS AND BENEFIT SHARING

The Protocol has its roots in the Convention on Biological Diversity, which reaffirms Parties' right to utilize their resources "*pursuant to their own environmental policies*" (Article 3) and determines the Parties' sovereign rights to regulate access to genetic resources under Article 15(1).[9] In accordance with Article 15(5), access to genetic resources requires the "*prior informed consent*" (PIC) of the country of origin. However, the rights of the country of origin are limited. According to Article 15(2) the Contracting Parties shall endeavour to create conditions to facilitate access to genetic resources by other Contracting Parties and not to impose restrictions that run counter to the objectives of the Convention. Further conditions for being granted access to genetic resources

4. See definitions in CBD Article 2 on use of terms.
5. Article 2 (c).
6. Cf. Article 5 (1).
7. Cf. Johannes Schei and Morten Walløe Tvedt (2010): *"Genetic Resources" in the CBD – The Wording, the Past and the Future*, Fridtjof Nansen Institute (FNI report 4/2010), at pp. 11. See also section 4 below on the relevant definitions in the Protocol.
8. Nonetheless, the book's interesting analyses illuminate many challenges and problems posed by the implementation of the Protocol both nationally and internationally, cf. Morten Walløe Tvedt (2010), (on Norwegian Genetic Ressource Law) in: *Norsk Genressursrett. Rettslige betingelser for innovasjon innenfor bio- og genteknologi*, Cappelen. Akademisk forlag (pp. 1-380). A forerunner for the book was published in Morten Walløe Tvedt (2005), (on exclusive property rights to genetic reosurces): Har noen eksklusive tinglige rettigheter til genetiske ressurcer i Norge?, *Retfærd 109* pp. 70, and (on the regulation of rights to genetic resources) in: En retspolitisk analyse av hvordan rettigheter til genetiske ressurcer kan reguleres?, *Retfærd 110* pp. 70.
9. The Convention is thoroughly examined in Veit Koester (1996), (on the Convention on Biological Diversity) in: Konventionen om den biologiske mangfoldighed (biodiversitetskonventionen) – en introduktion, Juristen pp. 272, and in Veit Koester (2006), (on international protection of biodiversity) in: "International beskyttelse af biodiversitet" in *Miljøretten 2. Arealanvendelse, natur og kulturbeskyttelse* (ed. Ellen Margrethe Basse), Jurist- og Økonomforbundets Forlag, pp. 82. As regards the background to the sovereignty provisions of the CBD, see above the first article, at pp. 274.

are *that:* the utilization of such resources is environmentally sound, cf. Article 15(2); access is on mutually agreed terms (MAT), cf. Article 15(4); and the benefits of the utilization are shared in a fair and equitable way on mutually agreed terms, cf. Article 15(7). The above provisions on access to genetic resources and benefit sharing from their utilization are normally referred to as access and benefit-sharing (ABS).

On the one hand, the Convention's regulation of access to genetic resources is based on the assumption that it is first and foremost of relevance to biodiversity-rich developing countries. On the other, the counterparts to providing access to genetic resources are industrialized countries' commitments to technology transfer (Article 16), information exchange and technical and scientific cooperation (Articles 17-18), and biotechnology (Article 19). These commitments are particularly relevant for industrialized countries.

Another important provision for ABS under the Convention, is Article 8(j) on respecting, preserving and maintaining, subject to national law, and as far as possible and as appropriate, knowledge, innovations and practices of indigenous and local communities (ILC).[10] Subject to the same conditions Parties are also obliged, *inter alia,* to promote the wider application of traditional knowledge (TK) with the approval and involvement of ILC as well as to encourage the equitable sharing of benefits arising from the utilization of TK[11].

The above provisions reflect two of the three objectives of CBD namely "*the sustainable use of* [the components of biodiversity] *and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.*"[12]

From early on it was rather clear that the CBD provisions on access and benefit-sharing, regardless of the fact that they were in principle quite clear, were too lapidary to function as a basis for implementing the benefit-sharing objective of the CBD. For example, there is no provision on monitoring and enforcing the users' obligation to seek and obtain prior informed consent for accessing genetic resources. Thereby, the rights of the developing countries are not fully protected under the CBD, which does not include clear international obligations of industrialized countries in this respect. Moreover, the CBD rules on benefit-sharing are, despite their obligatory character, far from being operational. In developing countries, there were great concerns and uncertainties on how to implement the rights to benefit-sharing. This situation made it difficult for corporations, which were seeking access to genetic resources, including in the form of bioprospecting, to obtain prior informed consent.[13] Fundamental questions that required clarification include: in a concerned developing country, which authorities have the responsibility to grant access, and how are such authorities to negotiate and establish mutually agreed terms (MAT)? A number of industrialized countries were firmly opposed to supplement the rules of the CBD with more detailed international provisions, especially of legally binding character, as well as to adopt national implementation measures, such as user measures. Hardly any industrialized country adopted legally binding implementation measures except Australia and Norway, and the latter only did so very late.

3. THE DEVELOPMENT OF AN INTERNATIONAL ABS REGIME UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY

The first ten years after the entry into force of the CBD on the 29 September 1993 were characterized by a series of legally non-binding decisions of various Conferences of the Parties that hardly played any role in the implementation of the relevant provisions of the CBD on access and benefit-sharing (ABS),[14] and by a number of developing countries adopting legislation on ABS.[15]

10. In addition to this, however, is also the CBDs definition in Article 2 of genetic material and genetic resources respectively, cf. section 1 above. See, furthermore, section 4 below.
11. See section 4.4 below.
12. CBD Article 1 provides in addition to the two above objectives for the conservation of biological diversity.
13. Bioprospecting is defined in C. Chiarolla (2010): *Making sense of the draft protocol on Access and Benefit Sharing for COP 10*, IDDRI, Paris, No. 07/201, 6 (note 13) (with a reference to M. Rogan-Finnemore (2005), cf. p. 11) as" a range of activities associated with the search for a novel biodiversity, whose component parts may be utilized in a product or process and developed for commercialization."
14. See section 2 above.
15. The book "Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity" (eds. Santiago Carrizosa et al.), IUCN, *Environmental Policy and Law Paper No. 54*, IUCN 2004, 41 (note 1) states that 41 countries had or where developing legislation on ABS in 1999. Of these, Australia was the only industrialized country, which demonstrates the importance of ABS regulation especially for biodiversity-rich countries.

The period from 2002 to 2004 was decisive for the further development of an ABS regime. In 2002 COP 6 adopted a set of guidelines on ABS, the so-called Bonn Guidelines, addressed at governments, users of genetic resources and those providing such resources.[16] According to the Guidelines, Parties with users of genetic resources should adopt legislative and other measures to promote the observance of both PIC and the mutually agreed terms (MAT) on the basis of which access to genetic resources is provided. The Guidelines, however, also contain a number of measures relevant to provider countries, not to say that the Guidelines are focusing mostly on obligations of provider countries.

Another important event was the World Summit on Sustainable Development (WSDS) in Johannesburg, South Africa, in 2002, where developing countries succeeded in including a provision in the Implementation Plan, which called for negotiating "*within the framework of the CBD, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources*."[17] An agreement was reached at COP 7 in 2004 to start negotiating an international regime on ABS, though the mandate was very vague since the regime "*could be composed of one or more instruments within a set of principles, norms, rules and decision-making procedures, legally-binding or and/or non-binding*."[18] The wording of the mandate reflected that most industrialized countries, as opposed to developing countries, did not want a legally binding regime. This affected the negotiations in the following years and hardly anyone with some understanding of the problem expected the negotiations to be easy.

The working group being in charge of the negotiations held nine formal meetings of which the ninth was held in multiple sessions spanning from March till October 2010, with some of these sessions held in smaller interregional negotiation groups. It was not until the second of these sessions in July 2010 that an agreement was reached to open formal negotiations on the basis of the draft text that had been presented at the first session in March 2010. The last session took place immediately preceding COP 10, but no agreement was reached on a number of controversial questions, which were still unresolved when COP 10 opened on 18 October 2010. The negotiations continued during COP 10 and resulted in a proposal by the Japanese presidency of a compromise package including, *inter alia,* proposals relating to the concepts of: utilization of genetic resources; derivatives; the Protocol's scope of application; and a number of other questions. Eventually, the proposed compromise package lead to the adoption of the Protocol, although without great enthusiasm.[19]

Even though prior to 2004 ABS had been already the object of academic interest, the decision in 2004 to start a negotiation process entailed a rich literature on this subject.[20] Undoubtedly, much of this literature can be seen as an academic contribution to the negotiations, while it is impossible to know whether it had an impact on the final result.[21] However, the subject matter was probably too complex and specific for the general literature on international environmental

16. *CBD Decision VI/24, Annex:* Bonn Guidelines On Access To Genetic Resources And Fair And Equitable Sharing Of Benefits Arising Out Of Their Utilization.

17. See, in particular, paragraph 44 (o) of the WSSD Implementation Plan. See, furthermore, Matthias Buck and Clara Hamilton (2011), "The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity", RECIEL 20 (1), pp. 47-61, containing also a brief account of the negotiation history of the Protocol (at pp. 49). For an account of the negotiation history with particular emphasis on developments in respect of the rights of indigenous and local communities, see Kabir Bavikatte and Daniel F. Robinson (2011), "Towards a People's History of the Law: Biocultural Jurisprudence and the Nagoya Protocol on Access and Benefit Sharing", *Law, Environment and Development Journal* (LEAD) Vol. 7/1, pp. 35-51, at pp. 40.

18. *Decision VII/19 on Access and benefit-sharing as related to genetic resources (article 15)*, Annex, Terms of Reference, para. b, Nature.

19. *Earth Negotiation Bulletin* (2010), Vol. 9 No. 544, available at: http://www.iisd.ca/biodiv/cop10/ . Generally, it was the position of many delegations "to take it or leave it." However, the Protocol is seen by several Parties as a successful result of COP 10. See, for instance, the Conclusions of the Council (*supra* note 3).

20. An early example is F. Hendrickx, V. Koester and Chr. Prip (1993)," Convention on Biological Diversity - Access to Genetic Resources: A Legal Analysis", *Environmental Policy and Law*, pp. 250.

21. Especially the *IUCN Environmental Policy and Law Papers* under the *ABS Series,* and the *Fridtjof Nansen Institute (FNI) Reports* should be mentioned. The following quotation of Tomme Young, one of the most prominent authors, provides a good background of these publications: "*After 12 years, legislative draftsmen and agencies are still attempting to grapple with complex legal problems that hinder the effective ABS implementation. ABS is in some ways "unique", particularly in its merger of very new concepts of commercial law and science with the goals of conservation, sustainable use and equity. New legal concepts and tools are needed, as well as new uses of existing tools. Legal innovation, however, is not an easy process*." See, Jorge Cabrera Medaglia and Christian López Silva (2007), *Addressing the Problems of Access: Protecting Sources, While Giving User Certainty* (ABS Series No. 1), IUCN *Environmental Policy and Law Paper* No. 67/1, IUCN, at p. 5.

law. Thus, analyses of the ABS rules of the CBD in textbooks on international environmental law are quite limited.[22]

4. SOME KEY ISSUES RELATING TO GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND BENEFIT-SHARING

4.1. Genetic resources

The utilization of genetic resources has numerous legal dimensions that are regulated both nationally and internationally by different instruments.[23] In his book, Morten Walløe Tvedt[24] demonstrates the complexity of this legal area, which derives its rules from *inter alia*: administrative law; property law; intellectual property law; environmental law; contract law.[25] To a wide extent it also reflects or is related to international agreements and EU-instruments or negotiations in progress in various international *fora*. Of course, the Nagoya Protocol does not regulate the use of genetic resources in all respects, but it does touch upon the most fundamental issues.[26]

The background to many provisions of the Protocol should be understood by examining the expected significance and value of genetic resources in a number of applications including, *inter alia*, in the pharmaceutical industry.[27] Therefore, the Protocol focuses on regulating access to and utilization of genetic resources with the view to implement the CBD's benefit-sharing objective.[28]

4.2. Utilization of genetic resources

The definition of genetic resources provided for in the CBD is not sufficient *per se* to regulate the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources." Without defining the concept of "utilization," every use of biological resources that meets the CBD definition's requirements would be covered, and thereby commodities that are the objects of extensive international trade.[29]

22. The following seven textbooks on international environmental law published in the period from 2000 to 2009 were examined. Beyerlin includes only a brief summary of CBD Article 15 in connection with Article 16. Ulrich Beyerlin (2000), *Umweltvölkerrecht,* Stämfli Verlag pp. 200 and pp. 260. Epiney und Scheily underline the obligation to implement CBD Article 15 *vis-à-vis* private actors. Astrid Epiney und Martin Scheily (2000), *Umweltvölkerrecht*, Verlag C.H. Beck, p. 291. Sands provides a brief summary of Articles 15 and 16 as well as of the Bonn Guidelines. Philippe Sands (2003), *Principles of International Environmental Law, Second Edition*, Cambridge University Press, pp. 519. Kiss and Shelton mention the relationship between ABS and ILC and refer also to the Bonn Guidelines. Alexandre Kiss and Dinah Shelton (2004), *International Environmental Law*, *Third Edition*, International Publishers, at pp. 432. Rayfuse considers the complex regulatory challenges related to CBD Article 15, *inter alia* in respect of TRIPs and the FAO Treaty on Plant Genetic Resources. Rosemary Rayfuse (2007), "Biological Resources", in (eds. Daniel Bodansky *et al.*): *The Oxford Handbook of International Environmental Law,* at pp. 378. Birnie, Boyle and Redgwell discuss how genetic resources may be utilized, but are otherwise concentrating on the relationship between CBD Article 15 and GATT , and conclude that Article 15 does seem to be insufficient in respect of the furtherance of sustainable development. Patricia Birnie, Alan Boyle and Catherine Redgwell (2009), *International Law and the Environment*, Oxford University Press, at pp. 803. Only Arbour and Lavallée provide for a detailed examination of CBD Article 15 and related articles, and a discussion of ABS in respect of ILCs. Jean-Maurice Arbour and Sophie Lavallée (2006), *Droit International de l'Environment*, Edition Yvon Blais/ Bruylant, at pp. 448 and pp473. The recent textbook, Ulrich Beyerlin and Thilo Marauhn (2011), *International Environmental Law*, Hart Publishing/Verlag C. H. Beck, 2011, provides at pp. 196 a very brief summary of both the Bonn Guidelines and the Nagoya Protocol.

23. In addition to international agreements concerning patents (cf. on TRIPs, section 4.4 below) and EU-legislation in that respect, i.e. the directive and the regulation mentioned infra note 135, the International Convention for the Protection of New Varieties of Plants (1991)(UPOV), the Budapest Treaty on International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977/1980), and the FAO Treaty referred to in section 6.2 can be mentioned among others. On the 1991 UPOV International Convention, see Graham Dutfield (2008), "Turning Plant Varieties into Intellectual Property: The UPOV Convention", in (eds. Geoff Tansey and Tasmin Rajotte): *The Future Control of Food: A Guide to International Negotiations and Rules in Intellectual Property, Biodiversity and Food Security,* Earthscan, at pp. 36, and Abeba Tadesse Gebreselassie (2012), *The Sustainability of Plants and Plant Intellectual Property Rights*, DJØF Publishing, Copenhagen, at pp. 123.

24. *Supra* note 8.

25. Danish law does not differ significantly from Norwegian law in these respects.

26. Human genetic resources are not covered by the Protocol. See paragraph 5 of *COP Decision X/1* (on the adoption of the Protocol) with a basis in *COP Decision II/11*, which determines that such resources are not covered by the CBD. Pathogens, however, are covered by the Protocol. See section 6.5 below.

27. An example of a drug stemming directly from a plant is Vincristine used to treat leukaemia, in particular in children. Cf. also e.g. Aphrodite Smagadi (2009), *Medical Bioprospecting. Policy Options for Access and Benefit-sharing*, British Institute of International and Comparative Law 2009, at pp. 16 and 22.

28. See, furthermore, section 5 below, and on the definition of genetic resources, section 1 above.

29. See the thorough analysis of both genetic material and genetic resources as legal concepts in *Morten Walløe*

On this basis, the concept of "utilization of genetic resources" is defined in Article 2 of the Protocol as the "*conduct* [of] *research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.*"[30] Therefore, the Protocol regulates access to genetic resources in connection with the defined utilizations and the sharing of the benefits arising out of such utilizations.[31]

4.3. Utilization of derivatives

The definition of "utilization of genetic resources" caused significant difficulties and was only settled as part of a compromise package during the final negotiations.[32] And hardly was this settled before conflicting understandings surfaced on whether the concept of "utilization of genetic resources" would also include the utilization of derivatives that are defined in Article 2(e) of the Protocol as "*a naturally occurring biochemical compound resulting from the genetic expression or metabolism of genetic resources, even if it does not contain functional units of heredity.*" It was part of the compromise package that the Protocol should contain a definition of derivatives, but while there was an agreement that products and commodities would not be covered by the Protocol, there was disagreement concerning derivatives. This disagreement was reflected in the "deliberate" or "constructive ambiguity" to the effect that derivatives are only mentioned in the definition section, but not in the operative provisions of the Protocol. For instance, derivatives can be proteins from gene expression or products of metabolism, including products which do not necessarily contain functional units of heredity such as latex and resins. Even though naturally occurring biochemical compositions do not contain functional units of heredity, they are used for the development of various products in medicine (e.g. insulin), food and cosmetics.

Article 3 of the Protocol concerns its scope and establishes that it covers genetic resources within the framework of the CBD and the sharing of the benefits arising out of the utilization of genetic resources. Due to the fact that derivatives are not directly referred to in Article 3 the question may be raised whether and to what extent derivatives are included in the scope of the Protocol. If derivatives contain functional units of heredity they are included since they fulfill the definitional requirements of genetic material, an element in the definition of genetic resources.[33] Most derivatives, however, do not contain functional units of heredity. Are such derivatives included? There is probably not much doubt that utilization of derivatives is included in the scope of the Protocol. The definition of utilization of genetic resources refers to the application of biotechnology,[34] and the definition of biotechnology to derivatives.[35] The above definition of derivatives also includes those that do not contain functional units of heredity. Hence, benefit-sharing requirements seem to be applicable to such derivatives. For instance, Article 5 (1) provides for benefit-sharing in conjunction with subsequent applications and commercialization of genetic resources. Accordingly, the problem of derivatives *per se* is probably relevant only in connection with regulated access, i.e. whether PIC requirements also apply to derivatives.

Apparently, it was very important for the EU that the Protocol would not cover derivatives as such. Pointing to the definition of utilization of genetic resources the Commission's report on the result of the Protocol negotiations concludes that the Protocol "*does not support self-standing prior informed consent requirements for access to biochemicals that are not anymore contained in genetic material*."[36] On the other hand an analysis of the provisions of the Protocol relevant to the issue of derivatives concludes that since the term utilization of genetic resources includes derivatives and the term utilization appears e.g. in Articles 3, 5(1), 6(1), and 17(1)(c), i.e. articles relating to scope, benefit-sharing, access, and monitoring, these provisions also apply to derivatives. Thus, the result of this analysis is, *inter alia*, that PIC is required for access to derivatives.[37] Others see the definition of derivatives

Tvedt (2010), (*supra* note 8), at pp. 33 and 37.

30. According to the CBD Article 2, biotechnology is defined as "*any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use*."

31. For an overview of what might be covered by this, see *Morten Walløe Tvedt* (2010), (*supra* note 8), pp. 45.

32. Cf. *Earth Negotiation Bulletin* (2010), (*supra* note 19), pp. 3 and section 3 above.

33. See section 1 above.

34. See section 4.2 above.

35. Cf. Article 2 (d) of the Protocol referring to Article 2 of the CBD.

36. On the Commission's report, (*infra* note 63), see section 6 below. Not surprisingly in view of the position of the authors during the negotiation of the Protocol. *M. Buck and C. Hamilton* (2011), (*supra* note 18), are concluding in the same manner (at p. 57).

37. Gurdial Singh Nijar (2011 a), The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: An Analysis, CEBLAW/Centre of Excellence for Biodiversity Law, University of Malay, pp. 24, available at: http://www.ceblaw.um.edu.my The author states, inter alia, that if derivatives are not included, then the majority of typical products developed on the basis of

as a possible supplement to the definition of genetic resources stating, however, simultaneously that it is not clear that benefit-sharing requires PIC or only takes place ensuing PIC. In the same vein, it is questioned how benefit-sharing would function without a necessary link to PIC procedures.[38] This observation is pertinent, since it is normally PIC which triggers mutually agreed terms (MAT) being the basis for sharing of benefits.

Altogether, the above question, to what extent the provisions of the Protocol are applicable to derivatives as such, is likely to remain a contentious issue as long as Parties do not arrive at some kind of a common understanding as evidenced by a COP-MOP decision.

4.4. Indigenous and local communities' traditional knowledge and its protection under intellectual property law

Difficult practical challenges concern: the protection of knowledge, practices and innovations (TK) of indigenous and local communities (ILC) embodying traditional lifestyles that are relevant for the sustainable use of biodiversity, the promotion of the wider utilization of such knowledge with their holders' approval and involvement; and the promotion of the equitable sharing of the benefits arising from their utilization.[39] Even though these obligations, being formally speaking legally binding, due to their conditional language might be comparable to soft law, they have resulted in a series of COP-decisions and the creation of a special working group solely occupied with their implementation.

CBD Article 8(j) does not regulate exclusively traditional knowledge on genetic resources. However, in practice the link between genetic resources and TK was quickly established, *inter alia*, because it could be documented that some medicinal drugs were developed based on pre-existing TK on the concerned genetic resources and, and because TK plays a vital role especially in ethnobotanical screenings.[40] This also led to the protection of TK being brought up in other international *fora*, such as the World Intellectual Property Organization (WIPO)—the UN's specialized agency for intellectual property rights—and the World Trade Organization (WTO). As early as 2000, WIPO set up an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) to discuss this matter. In 2004 a draft was submitted on protection of traditional knowledge and traditional cultural expressions against misappropriation and misuse, and in 2009 the WIPO General Assembly decided to extend the mandate of IGC to the possible drafting of legally binding instruments.[41] In WTO the discussions have revolved around the Agreement on Trade-Related Aspects of Property Rights (TRIPs), whose patent provisions are perceived by developing countries as potentially leading to biopiracy and misappropriation of TK. Moreover, according to developing countries, there should be provisions requiring that patent applications contain information on the origin of genetic material and TK that is utilized in the invention (i.e. disclosure requirements), and evidence of obtaining PIC and establishing benefit-sharing as requirements for patentability. In short, developing countries want the benefit-sharing principles of the CBD to be incorporated into the TRIPs Agreement, which is opposed by industrialized countries, with some of them preferring this issue to be treated in WIPO.[42] At present, the negotiations on disclosure requirements seem to be deadlocked.[43]

Under "scope", Article 3 states that the Protocol also applies to "*traditional knowledge associated with genetic resources within the scope of the Convention and the benefits arising from the utilization of such knowledge.*" The Protocol's operative provisions on TK reflect this. Hence, access to and

genetic resources would be excluded. In line with this interpretation is one of the participants of a seminar in Paris, organized by IDDRI, cf. Mireille Jardin and Claudio Chiarolla in International Law and Policy Vol. 41 No. 2 (2011), pp. 70 (note 2), concluding that the value of genetic resources are not in the genes but the proteins that the genes produce or are intended to produce. See equally, Gurdial Singh Nijar (2011 b), *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries,* Research Papers 36, South Centre/CEBLAW.

38. Nagoya Protocol on Access and Benefit Sharing – Technical Brief, *Union for Ethical BioTrade*, available at: http://www.ethicalbiotrade.org/resources

39. Cf. CBD Article 8 (j) and section 2 above.

40. *Aphrodite Smagadi (2009),* (*supra* note 27), at pp. 25-28, and Graham Dutfield (2011), "A Critical Analysis of the Debate on Traditional Knowledge, Drug Discovery and Drug-based Biopiracy", *European Intellectual Property Revue*, Vol. 33 Issue 4, pp. 237-243.

41. See section 6.7 below.

42. Cf. Aphrodite Smagadi (2009) (ibid.), at pp. 99, Elisa Morgera and Elsa Tsioumani (2010), "The Evolution of Benefit Sharing: Linking Biodiversity and Community Livelihoods," RECIEL 19 (2), 169, and David Visas-Egui (2012), *Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee (IGC),* Issue Paper No. 34, International Centre for Trade and Sustainable Development, Switzerland, at pp. 17 and pp. 30.

43. The issue of disclosure is further referred to in section 6.7 below.

benefit-sharing from traditional knowledge associated with genetic resources is formally put on same footing as ABS in connection with genetic resources.

However, the challenges associated with the protection of TK and the sharing of the benefits arising from its utilization complicates the international regulation of access and benefit-sharing. A special challenge relates to implementing human rights-related aspects of TK protection, including certain rights of collective nature, which seems to be emerging in international law.[44] Besides, a key issue is whether the Protocol does contribute to the establishing and protecting such rights, including the rights of indigenous and local communities over their genetic resources.

Compared with the ILC' rights according to CBD the rights as provided for by the Protocol are both more firmly established and more extensive. Article 8 (j) of the CBD, being the only article of CBD addressing ILC, is limited to the respecting, preserving and maintaining TK, promoting its wider application with the approval and involvement of ILC, and encouraging equitable sharing of the benefits arising from the utilization of TK. Furthermore, the rights are subject to national legislation, and the obligations are qualified by "as far as possible and as appropriate".[45] The obligations of the Protocol relating to ILC and/or TK[46] are not qualified in the same manner as Article 8 (j). In addition, some provisions of the Protocol are addressing also access to and benefit-sharing arising from the utilization of genetic resources that are held by ILC.[47]

While the rights of ILC provided for by the Protocol are formulated in a rather absolute and direct manner most of them are simultaneously qualified by a reference to domestic law.[48] Article 5 (5) on sharing of the benefits arising from the utilization of TK associated with genetic resources,[49] however, does not contain such reference.[50] Hence, the question arises whether the commitment of Parties to take measures in order that those benefits are shared in a fair and equitable way with ILC is only due, if the Party concerned has domestic legislation to such effect. It may be argued that the reference in the provision to ILC "*holding such knowledge*" (i.e. TK) entails an implicit reference to domestic law. The explicit references to domestic legislation in other provisions seem, however, to justify the conclusion that the omission of such reference in Article 5 (5) is deliberate. Furthermore, the preamble states that nothing in the protocol "shall be construed" as diminishing or extinguishing existing rights of ILCs and it also contains a number of other considerations on these rights.

The above question will not be answered in further detail here, but it deserves attention and it is certainly going to be the object of future analyses.[51] Incidentally, neither the Convention nor the Protocol contains a definition of TK. In the above mentioned 2004 WIPO draft text on the term TK refers "*to the content of knowledge resulting from*

44. These challenges are analysed in Gurdial Singh Nijar (2010), "Incorporating Traditional Knowledge in an International Regime on Access to Benefit Sharing: Problems and Prospects," *European Journal of International Law Vol. 21 No. 2,* at p. 457. Herein, it is also with reference to the *United Nations Declaration on the Rights of Indigenous Peoples* (UNGA Res. 61/295), (UNDRIP) and state practice implied that the requirement of PIC from ILC as a condition for access to and utilization of their TK might be considered customary international law. Ibid. at pp. 460-461.

45. See section 2 above. See also the analysis in *K. Bavikatte and D.F. Robinson* (2011), (*supra* note 18), concluding, at p. 41, that the rights within the CBD are "enervated".

46. In addition to Article 3, (see section 4.3 above), mainly Articles 5 (2) and (5), 6 (2), 7, and 12, cf. section 5 below.

47. Articles 5 (2) and 6 (2). During the negotiations the issue on whether a legal recognition of the right of ILC over their TK might strengthen their claims over the associated genetic resources was rather controversial, cf. Claudio Chiarolla (2010), *Making Sense of the Draft Protocol on Access and Benefit Sharing for COP,* Iddri, Working Papers, N° 07/2010, pp. 7-8.

48. Articles 5 (2), 6 (2), 6 (3) (f), 7 (1), 12 (1) and 16 (1).

49. The fact that the term "utilization of TK associated with genetic resources" is not defined by the Protocol needs to be addressed on the domestic level and might also be an issue suitable for being considered by the COP-MOP.

50. Formally speaking, this also applies to Article 3, see section 4.3 above.

51. On Article 8(j), including from a human rights perspective, see Veit Koester (1996), *Supra* note 9, at p. 281 and Athanasious Yupsanis (2010), "ILO Convention No. 169 Concerning Indigenous and Tribal Peoples in Independent Countries 1989-2009: An overview," *Nordic Journal of International Law,* Vol. 79 No. 3, at p. 433. This Convention is relevant but it is only ratified by about 20 states. The *United Nations Declaration on the Rights of Indigenous Peoples* (UNDRIP), which is mentioned in the preamble of the Protocol, is also important, especially its Article 31 that provides for *"the right of indigenous peoples to maintain, control, protect and develop their … traditional knowledge, as well as the manifestations of their science, technologies and cultures, including … genetic resources, seeds, medicines, knowledge of the properties of fauna and flora … They have also the right to maintain, control, protect and develop their intellectual property over such … traditional knowledge …".* UNDRIP is examined in Karen Engle (2011), "On Fragile Architecture: The UN Declaration on the Right of Indigenous Peoples in the Context of Human Rights," *European Journal of International Law*, Vol. 22 No. 1, at p. 141. *K. Bavikatte and D. F. Robinson* (2011), (*supra* note 18), argue at pp. 46-47 that the words "established rights" in Article 6 (2) of the Protocol leave it to interpretation as to whether the rights of indigenous and local communities to grant access to genetic resources are established in national or international law.

intellectual activity in a traditional context, and includes the knowledge, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional life styles of indigenous and local communities, or codified knowledge systems passed between generations. It is not limited to any specific technical field and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources."[52] This definition illustrates that TK can be an expression of collective immaterial rights.

5. THE CONTENT OF THE NAGOYA PROTOCOL

The main content of the Protocol comprises three related elements, namely access to genetic resources, benefit-sharing and compliance. On each of these elements, the Protocol contains specific provisions, albeit many of them are formulated more as general principles than as operational rules. Accordingly, there is a need to develop guidelines, standards, *etc.* in order to provide for their practical implementation. The Protocol's provisions will be outlined with emphasis on the above three elements.[53]

Articles 1-4 concern the Protocol's objectives, use of terms, its scope and the relationship with other international agreements. The provision on the objectives further develops the Protocol's title.[54]

Article 5 contains the main principles on benefit-sharing. Paragraph 1 states the principle of a fair and equitable sharing of the benefits arising from the utilization of genetic resources "*as well as subsequent applications and commercialization … with the Party providing such resources or a Party that has acquired the genetic resources in accordance with the convention. Such sharing shall be on mutually agreed terms.*" Paragraph 3 contains the obligation to implement this principle. Paragraphs 2 and 5 determine the Parties' obligation to take legislative and other measures with a view to sharing benefits with indigenous and local communities when genetic resources "*that are held*" by them or TK associated with genetic resources is utilized, on mutually agreed terms. Article 5 is supplemented by an annex on monetary and non-monetary benefits, which is not an exhaustive list and provides relevant examples.

The main provision on access is Article 6, which contains a sort of summary of CBD Article 15(1) and (5) on the sovereign rights of states over natural resources and PIC. In addition to this, and contrary to the CBD, it subjects PIC to "*domestic access and benefit-sharing legislation or regulatory requirements.*"

Article 6(1) does not state whether its access provisions apply also to access to genetic resources and their utilization when such resources are contained in biological materials that are exported from the country of origin as commodities, e.g. as food. However, there are no reasons for assuming that this is not the case. As mentioned in section 4.3 above, the Protocol does not concern products or commodities that are made of biological materials as such, if the genetic resources contained therein are not used for the purposes defined in the Protocol.

Article 6(2) provides certain obligations to require the PIC or approval and involvement of indigenous and local communities "*where they have the established right to grant access to such resources.*" These obligations are further developed in Article 6(3) on establishing procedures for obtaining ILC' prior informed consent and supplemented by Article 7 on the PIC or approval and involvement

52. Cf., *ABS – Management Tool. Best Practice Standard and Handbook for Implementing Genetic Resource Access and Benefit-Sharing Activities (2007)*, Swiss Confederation, Federal Department of Economic Affairs, Volume 1, at p. 4. WIPO has compiled a database of legal texts on the protection of TK and texts about genetic resources. According to Simra Sevim (2011), "Traditional Medicin", Environmental Policy and Law, at p. 136, referring to WIPO, *Intellectual Property and Traditional Knowledge, Booklet no. 2* at p. 6, the adjective "traditional" in the above definition does not mean that the knowledge is ancient or inert; rather it is a dynamic and evolving part of the contemporary lives of many communities. Options for definition of TK as a result of the meetings in May and July 2011 of the WIPO Intergovernmental Committee, referred to above, are included in Annex B to *Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)*, doc. WO/GA/40/7, prepared by the WIPO Secretariat available at http://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_40/wo_ga_40_7.pdf.

53. The Protocol comprises a preamble with 27 considerations, 36 operative provisions and one annex. For a detailed analysis of the Protocol, see: Elsa Tsioumani (2010), "Access and Benefit Sharing – The Nagoya Protocol," *Environmental Policy and Law 40/6*, at pp. 288, and Evanson Chege Kamau, Bevis Fedder and Gerd Winter (2011), "The Nagoya Protocol on Access and Benefit Sharing: What is New and What are the Implications for Provider and User Countries and the Scientific Community", *Law, Environment and Development Journal (LEAD)*, Vol. 6/3, pp. 248-262, at pp. 250. For an extensively revised ("stark überarbeitete") version of the article, see Gerd Winter und Evanson Chege Kamau (2011), "Von Biopiraterei zu Austausch und Kooperation", *Archiv des Völkerrechts* Band 49 Heft 4.

54. On Article 2, see section 4.2 above; on Article 3, see section 4.4 above and section 6.2 below; on Article 4, see section 6.4 below.

of ILCs when access to their TK is sought, and on establishing MAT.

Article 6(3) contains a list of requirements for the legislation of Parties that choose to subject access to their genetic resources to PIC, which provide for, *inter alia*: legal certainty, clarity and transparency; non-arbitrary rules and procedures on accessing genetic resources; a written decision by a competent authority; "*the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-Sharing Clearing-House accordingly*;" and clear rules and procedures for requiring and establishing MAT for benefit-sharing. In accordance to Article 6(3)(g), these terms may contain, *inter alia*, a dispute settlement clause and conditions concerning benefit-sharing, including in relation to intellectual property rights, subsequent third-party use and change of intent.

These provisions should be read in conjunction with Article 18(1), which states that each Party shall encourage providers and users of genetic resources (and/or traditional knowledge associated with genetic resources) to include provisions in mutually agreed terms to cover dispute resolution, jurisdictional rules, the applicable law, *etc.* Besides, in accordance with Article 18(2), each Party has the obligation to ensure access to justice for the enforcement of the MAT under its legal systems.

The obligations concerning the ILC and their rights in relation to genetic resources and TK is supplemented by Article 12, which contains, *inter alia*, a provision on establishing mechanisms to inform potential users of TK associated with genetic resources about their obligations in relation to ABS.

Article 8 aims at promoting research that contributes to biodiversity conservation and sustainable development, *inter alia*, by simplifying rules on access for non-commercial research purposes. Besides, due regard has to be paid to food security and to "*present or imminent emergencies*" by taking into account the "*need for expeditious access to genetic resources"* and expeditious benefit-sharing, including in the form of "*access to affordable treatments by those in need.*"

The user Parties' main obligations can be found in Articles 15 to 17. Article 15 establishes that Parties must to take appropriate, effective and proportionate measures to ensure that genetic resources utilised within their jurisdictions have been accessed in accordance with PIC, and that MAT have been established, as required by the domestic ABS legislation or regulatory requirements of the Party of origin. Furthermore, there is an obligation to address cases on non-compliance and to cooperate on this. Analogous obligations can be found in Article 16 on compliance with domestic ABS legislation regarding TK associated with genetic resources.

Article 17 contains provisions on monitoring the utilization of genetic resources. Therefore, this article mainly supplements Article 15 and it predominantly targets "user countries." It contains two important mechanisms. First, it requires designating one or more so-called checkpoints, which have to be effective and relevant in relation to the utilization of genetic resources or the gathering of relevant information "*at any stage of research, development, innovation, and pre-commercialization.*" Checkpoints have to collect or receive relevant information on PIC, the source of the genetic resources, the mutually agreed terms (MAT) and/or the utilization of genetic resources, and Parties shall require users to provide such information at checkpoints. This information, including the relevant permits or equivalent, must be provided to the relevant national authorities, the Party providing PIC and the ABS Clearing House, as appropriate.

Second, the Protocol institutionalises an "*internationally recognized certificate of compliance*".[55] The certificate serves as evidence that the genetic resource which it covers has been accessed in accordance with PIC and that MAT have been established, as required by the domestic ABS legislation of the Party from which the genetic resource stems. The certificate is based on the decision/permit, which is mentioned in Article 6(3).[56] Article 17(4) contains the minimum information that the decision/permit shall contain when it is not confidential. However, Article 17 only concerns the utilization of genetic resources and not the utilization of TK associated with them.

The obligation to respect the mutually agreed terms is not an obligation under public international law but a contractual obligation, which is part of private international law because of the international dimension of such contract. This is also why compliance with MAT-related obligations is not covered by Article 17, but it is provided for in Article 18(2) and (3), which states: "*Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of dispute arising from mutually agreed terms. Each Party shall take effective measures, as appropriate, regarding: (a) access to justice; and (b) the utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.*"

55. Cf. Article 17(3).

56. On the certificate, see also section 6.8 below.

According to Article 18(4), the effectiveness of the provisions of this article has to be reviewed by the Conference of the Parties serving as the meeting of the Parties to the Protocol four years after the entry into force of the Protocol. The expression "*access to justice*" is presumably inspired by Article 9(3) of the Aarhus Convention,[57] but the scope of this provision is unclear. This is because it is not specified whether such expression will also cover access to legal aid, which is a relevant matter since most often it will be the Party granting access to genetic resources and TK that will be the weaker Party. Other relevant questions are whether (and under which terms) the judgments delivered by a court in a contracting Party will be recognized by another Party, and whether they will be executed by or in this Party, especially if the latter is a user country and the former is the provider of the genetic resources and TK.[58]

Additionally, the Protocol contains provisions on, *inter alia*: considering establishing a Global Multilateral Benefit-Sharing Mechanism; transboundary cooperation; national focal points and competent national authorities; the establishment of a Clearing-House for ABS; model contractual clauses; codes of conduct; awareness raising and capacity; technology transfer; non-parties; the financial mechanism;[59] and establishing a compliance mechanism.[60] Other Protocol's provisions are of institutional character or contain final clauses.[61] As regards dispute resolution, the provisions of CBD will apply.[62]

6. THE NAGOYA PROTOCOL AS A LEGAL INSTRUMENT

6.1. The Protocol rules in general

According to the EU Commission's report on the result of the negotiations, the Protocol establishes a clear and transparent framework on how to access genetic resources and TK associated with them for the purpose of research and development and how to provide for benefit-sharing.[63] The report also highlights that the Protocol contains clear obligations that its Parties are to make sure that users under their jurisdiction respect the relevant "domestic ABS legislation or regulatory requirements of the other Party" from where the resources originate.

The above evaluation of the Protocol is remarkably more optimistic than other available analyses. For instance, the analysis made by a chief negotiator of the Like-Minded Asia Pacific Group concludes that the Protocol is legally lacking in

57. Article 9 on Access to Justice of the 1998 Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters provides for a review procedure before a court of law or another independent and impartial body established by law to safeguard the rights afforded in the Convention. The procedures shall, *inter alia*, provide adequate remedies, including injunctive relief as appropriate, and be fair, equitable, timely and not prohibitively expensive.

58. See, Claudio Chiarolla (2011), The Role of Private International Law under the Nagoya Protocol, prepared for the conference: The 2010 Nagoya Protocol on Access and Benefit-sharing: Implications for International Law and Implementation Challenges (Edinburgh 2-3 December 2011), at pp. 15-17.

59. Respectively Articles 10, 11, 13, 14 and 19-25.

60. Cf. Article 30. The abovementioned provisions in Articles 15 to 17 on compliance aim at securing that those utilizing genetic resources and TK observe the applicable ABS requirements provided for in the applicable domestic legislation or regulatory requirements, whilst Article 30 aims at the compliance of Parties' obligations including those pertaining to Articles 15-17. Since ILC hold a central position within the framework of the Protocol and may even have certain rights flowing directly from its provisions (see section 4.3 above), it would be fair and justifiable to include in the scope of the future compliance mechanism possibilities of considering complains by ILC on non-compliance with provisions of the Protocol establishing or aiming at protecting rights of ILC. Such trigger of the mechanism would be in line with the trigger by members of the public of the compliance mechanism of the Aarhus Convention (*supra* note 57), which provides such rights for members of the public, see e.g. Veit Koester (2005), "Compliance Review under the Aarhus Convention: A Rather Unique Compliance Mechanism", *Journal for European Environment* and *Planning Law*, 2/2005, pp. 31-44. According to a synthesis of views and possible draft elements and options for the compliance mechanism of the Protocol, prepared by the CBD Secretariat, some submissions reflect on the possibility of incorporating a trigger by members of the public, including by ILC, in the procedures of the compliance mechanism (see para. 56 of doc. *UNEP/CBD/ABS/EM-comp/1/2*, 22 December 2011). It is, however, most unlikely that such procedures are going to be included, since States are, generally speaking, extremely reluctant to offer members of the public possibilities of raising issues at the international level on non-compliance with States' international obligations which are not related to human rights instruments, see e.g. Veit Koester (2009), "The Compliance Mechanisms of the Aarhus Convention and the Cartagena Protocol on Biosafety: A Comparative Analysis of the Negotiation Histories and their Outcomes", in *Tulio Treves et al.:* Non-Compliance Procedures and the Effectiveness of International Environmental Agreements, Asser Press, the Hague, at p. 296. On the negotiations of the future ABS compliance mechanism at the first meeting (5-10 June 2011) of the Intergovernmental Committee established by COP Decision XI (cf. section 6.2 below), see Elisa Morgera (2011), "All about Compliance", *Environmental Policy and Law*, pp. 189.

61. Respectively Articles 26-29, 31 and Articles 32-36.

62. Cf. CBD Article 27(5).

63. Council of the European Union, *Meeting Document of 12 Nov. 2010, DS1803/10, Annex*.

several respects.[64] On the other hand, a review by an independent European think-tank highlights that the Protocol provides considerable discretion concerning how it may be interpreted.[65]

A complete picture of the problems that the Protocol's implementation may raise at the domestic level and their possible solutions still appear to be out of sight. The implementing work has hardly started yet. Nor this article can outline all the outstanding questions that need urgent attention, including on issues that are remained unresolved because no agreement could be fully reached in Nagoya.[66] The following key questions will be considered, *inter alia*, with particular references to the report of the EU Commission:

- genetic resources and TK regulated by the Protocol;
- resources acquired before the Protocol;
- the relationship between the Protocol and other instruments
- pathogens
- research, in particular, non-commercial research
- the relationship between the Protocol and patent law
- internationally recognized certificate of compliance

6.2. Which genetic resources and TK does the Protocol cover?

As regards genetic resources, Article 3 defines the Protocol's scope by referencing the provision of Article 15 (1) of CBD. Namely it will cover genetic resources over which the Parties have sovereign rights and the sharing of the benefits arising from their utilization.[67] As a result of this the Protocol does not apply to genetic resources over which the Parties may not exercise their sovereign rights, e.g. in areas beyond national jurisdiction. The principles of Article 3, which are further elaborated in Articles 5(1) and 6(1) both of which repeat the wording of CBD Article 15(3), respectively state that the provider Party that is entitled to benefit-sharing and to grant its prior informed consent "*...is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention.*" Terms defined in Article 2 of CBD shall according to Article 2 of the Protocol apply to the latter. Hence, "country of origin" means the country which possesses the genetic resources in *in-situ* conditions, i.e. where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

However, the CBD did not solve the question of benefit-sharing concerning genetic resources 'belonging' to multiple Parties or genetic resources and TK where the PIC procedure is not applicable because no sovereign rights exist.

This issue was only partly solved by the FAO Treaty on Plant Genetic Resources (ITPGRFA), which establishes a Multilateral System of access and benefit-sharing that covers a number of important food crops and forage species. These species are particularly important for food security and many of them are held in an international network of genebanks that makes publicly available their collections of plant genetic resources within the Multilateral System of the FAO Treaty which, furthermore, qualifies as a specialised international access and benefit-sharing instrument under Article 4(4).[68] These resources are to a great extent

64. *G.S. Nijar* (2011 a), *Supra* note 37, at pp. 31. In certain aspects, Nijar's analysis seems politically motivated and should be taken with caution. However, the same applies to the EU Commission's evaluation.

65. Raphaël Billé, Claudio Chiarolla and Lucien Chabason (2010), "COP 10 in Nagoya: a success for global biodiversity governance?", *Synthèses IDDRI No. 06,* 10 December 2010. The results of an *Informal Expert Consultation* on the "further elaboration" of the Nagoya Protocol very much confirm that there are various interpretation problems which have still to be addressed. See Kabir Bavikatte, Claudio Chiarolla, Balakrishan Pisupati and Carmen Richerzhagen (2011), *Outcomes of Informal Expert Consultation on further elaboration of the Nagoya Protocol on Access to genetic resources and Benefit Sharing*, jointly organized by UNEP and Government of India, (Chennai, 13 – 15 February 2011).

66. During the negotiations of the Protocol, some critical questions were set aside or "parked" in the preamble of the Protocol. However, some of them were not eventually solved by Parties. For instance, this applies to genetic resources and TK that are transboundary in nature (para. 12) and to pathogens (para. 19).

67. According to Article 3 the Protocol also applies to TK associated with genetic resources and to the sharing of the benefits arising from the utilization of TK.

68. See furthermore section 6.4 below. For more on the FAO Treaty, see Gerald Moore and Witold Tymowski (2007), Explanatory Guide to the International Treaty on Plant Genetic Resources for Food and Agriculture, IUCN *Environmental Policy and Law Paper* No. 57, IUCN, and Michael Halewood and Kent Knadozie (2008), "Giving Priority to the Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)", in (eds. Geoff Tanseay and Tasnim Rajotte): The Future Control of Food: A Guide to International Negotiations and Rules in Intellectual Property, Biodiversity and Food Security, Earthscan, at pp. 115. Particulary on the contract based SMTA (Standard Material Transfer Agreement), see Morten Tvedt Walløe (2010), (*supra* note 8), at p. 348, and Elisa Morgera and Elsa Tsioumani (2010), (*supra* note 42), at pp. 258. Cf. also Tomme R. Young (2011), "The Treaty's Role Following Nagoya", Environmental Policy and Law 41/2, at pp. 71. For details of the Multilateral System of

unfit for being regulated by means of the ABS-provisions of the Protocol, because the genetic material has been modified over time, e.g. by crop improvement, crossing or propagation in plant breeding. Hence, their existence is closely linked to human activities.[69] Considerations of a similar nature may apply to animal genetic resources for food and agriculture.[70] Possibly, the mechanism foreseen by the Protocol in Article 10 (Global Multilateral Benefit-Sharing Mechanism) may also provide useful for implementing benefit-sharing from genetic resources other than those covered by the FAO Treaty's Multilateral System and collected before the entry into force of the CBD.

Multiple Parties' "ownership" of genetic resources or TK held by ILC in several Parties is addressed by Article 11. The issue, however, is only partly resolved by Article 11, because Parties' obligations are limited to *"endeavor to cooperate … with a view of implementing this Protocol"*. Genetic resources that occur in transboundary situations are also covered by the above Article 10 which, furthermore, applies to genetic resources for which it is not possible to grant or obtain PIC. Article 10 is presupposing that "*the Parties have to consider the need and modalities of a global multilateral benefit-sharing mechanism*" whose benefits shall be used to support the conservation of biological diversity and the sustainable use of its components.

The mechanism of Article 10 is going to be discussed at the second meeting of the Intergovernmental Committee established by COP Decision X/1 with the mandate to preparing the ratification of the Protocol and its entry into effect. The relationship between the Global Multilateral Benefit-Sharing Mechanism and genetic resources outside of national jurisdiction such as Antarctica, the High Seas and the Deep Seabed has to be further considered during the negotiation process. The legal status of the genetic resources in the deep seabed is currently discussed under the auspices of the UN General Assembly within the framework of UNCLOS (United Nations Convention on the Law of the Sea). UNCLOS does not contain any rule on benefit-sharing for genetic resources nor it is supplemented by a special agreement, such as the one concerning "the Area" and the exploitation of raw materials in the deep seabed. Therefore, the *status quo* is that access and utilization is in principle free.[71] In addition, the extent to which a multilateral mechanism established under Article 10 may cover benefit-sharing from the utilization of TK that is publicly available will also need further clarification.[72]

6.3. Are genetic resources acquired prior to the Protocol covered?

The EU Commission's report states that the Protocol will not apply to genetic resources acquired before the Protocol's entry into effect. The argument that is set forth is that nothing indicates that it was the intention of the Parties to give the Protocol retroactive force, while the key provisions of Articles 5(1) and 6(1) refer to the *"Party providing such resources"*. This term clearly means that such Party must be understood as a State that has ratified the Protocol. However, it is arguable whether the Commission's interpretation holds true.

The Commission's interpretation appears to be consistent only as far as the relations *inter partes* are concerned, in accordance with the principle

the FAO Treaty, see Evanson Chege Kamau (2011), The Multilateral System of the FAO Treaty: ABS Lessons for Genetic Diversity of Global Importance available at http://www.planttreaty.org/content/multilateral-system-fao-treaty-abs-lessons-genetic-diversity-global-importance. The Multilateral System of the FAO Treaty has been critically analysed after its first five years of implementation in Claudio Chiarolla and Stefan Jungcurt (2011), Outstanding Issues on Access and Benefit Sharing under the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture, Background Study Paper, The Berne Declaration, Sweitz og Utviklingsfondet, Norge.

69. *M. Buck and C. Hamilton (2011)*, (*Supra* note 11), observes at p. 58 that the Protocol applies if an Annex I crop of the FAO Treaty were to be used for a purpose unrelated to the Treaty. The above considerations, however, may also be relevant in such circumstances.

70. Cf. EU Submission on sectorial and cross-sectorial model contractual clauses for mutually agreed terms and existing guidelines and codes of conduct related to access and benefit-sharing; and measures to raise awareness of access and benefit-sharing (11 March 2011) to the CBD Secretariat referring to an annex (Annex 3) containing a summary report of the International Technical Expert Workshop exploring the need for specific measures for ABS of animal genetic resources for food and agriculture (Wageningen, 8-10 December 2010).

71. See Charlotte Salpin and Valentine Germani (2007), "Patenting of Research Results Related to Genetic Resources from Areas beyond National Jurisdiction: The Crossroads of the Law of the Sea and Intellectual Property Law," *RECIEL 16 (1)*, at p. 12; Lyle Glowka (2010) "Evolving Perspectives on the International Seabed Area's Genetic Resources: Fifteen Years after the "Deepest of Ironees", in Davor Vidar (ed.): *Law, Technology and Science for Oceans in Globalization*, Leiden/Boston: Martinus Nijhoff Publishers/Brill, pp. 397, and Arianna Broggiato (2011), "Marine Genetic Resources beyond National Jurisdiction – Coordination and Harmonization of Governance Regimes," *Environmental Policy and Law 41/1,* at p. 35. The latter also describes the latest development concerning Antarctica.

72. On Article 10, see Morten Walløe Tvedt (2011), *A Report from the First Reflection Meeting on the Global Multilateral Benefit-Sharing Mechanism*, FNI/Report 10/2011, Fridtjof Nansen Institute 2011.

of Article 41(1)(b)(i) of VCLT (Vienna Convention on the Law of Treaties). In other words, a Protocol Party may not claim to a non-Protocol Party that is Party to the CBD that the demand for PIC only applies to genetic resources acquired after the entry into force of the Protocol and not to genetic resources acquired after the entry into force of the CBD but prior to the entry into force of the Protocol.[73]

One may also question whether the fact that a state ratifies the Protocol may entail that such Party would no longer be able to enforce its rights in accordance with the CBD with respect to genetic resources illegally acquired after the CBD entered into force. For instance, it is hard to explain why the commercial utilization of genetic resources, for which access was granted only for research purposes prior to the Protocol's entry into effect, should not be covered by the Protocol. Article 15 (5) of CBD requiring PIC for access to genetic resources continues to govern the relationship between a provider country being a Party to CBD, but not a Party to the Protocol, and a user country being a Party to the Protocol.[74] Hence, Article 15 (5) is also applicable to genetic resources being acquired after the entry into force of the Protocol.[75] Presumably, nor does the Protocol entail, that a provider country being a Party to the Protocol is released from its obligations under the CBD in relation to a user country being a Party to the CBD but not to the Protocol. Such provider country is still under the obligations of CBD Article 15 (2) to facilitate access to genetic resources. Accordingly, it cannot deny access by referring only to the fact that the user country is not a Party to the Protocol.

6.4. The relationship between the Protocol and other instruments

Article 4 contains provisions on the relationship between the Protocol and other instruments (i.e. a so-called relationship or savings clause).[76] Article 4 (1) is regulating the relationship with any existing international agreement encapsulating three rules/principles: First, that the provisions of the Protocol shall not affect the rights and obligations deriving from other international agreements; second, that this is "*except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity*"; and third, that no hierarchy between the Protocol and other international instruments is intended.[77] The second statement suggests that if serious damage may be caused there is in fact a hierarchy in favor of the Protocol. Article 4 (1) is to some extent supplemented by the positive obligation in the first sentence of Article 4 (3) to the effect that "*the Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol*", since the notion of instruments also includes agreements. Article 4 (2) is safeguarding the rights of Parties to develop and implement *"other relevant international agreements, including other specialized access and benefit-sharing agreements."* However, such agreements must be *"supportive of and [do] not run counter to the objectives of the Convention and this Protocol."* This provision is supplemented by Article 4 (4) referring to specialized access and benefit-sharing instruments. When such instrument applies and is consistent with and does not run counter to the obligations of the Convention and the Protocol, the Protocol *"does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument."* The FAO Treaty[78] is undoubtedly a specialized international access and benefit-sharing instrument, but it is not clear whether the term

73. In accordance with the principles of public international law (VCLT Article 28), the CBD does not have retroactive application. Therefore, it does not apply to genetic resources, which were, prior to the entry into force of the CBD, held outside of the country of origin, e.g. in botanical gardens or genetic banks. On the Nordic Gene Bank, see Nordic Council of Ministers (2003): *Access and Rights to Genetic Resources. A Nordic Approach*, at pp. 15, 99 and 159.

74. Also, the other provisions of Article 15 are applicable, *inter alia*, paragraph 4 on MAT and paragraph 7 on benefit-sharing, see section 2 above.

75. However, such provider country cannot, of course, enforce user country compliance measures under the Protocol Articles 15 and 17. Arguably, the same applies to provider countries being Parties to the Protocol without having adopted ABS legislation, see *Gurdial Singh Nijar* (2011 b), *(Supra* note 37), at p. 2.

76. Such clauses may be considered as legal tools to address potential tensions between competing or conflicting norms. In particular, this is relevant to the extent clauses refer to the principle of mutually supportiveness, as indeed Article 4 (3) of the Protocol does. The principle of mutual supportiveness has attracted some academic interest. See Riccardo Pavoni (2010), "Mutual Supportiveness as a Principle of Interpretation and Law-Making: A Watershed for the 'WTO and Competing Regimes Debate'?", European Journal of International Law, Vol. 21 No. 3, pp. 649-679, with numerous references as well as a discussion (at pp. 655) of the largely debated clause of the CBD in its Article 22 (1), from which the two first rules/principles of Article 4 (1) of the Protocol (see below) originate. Altogether Article 4 of the Protocol partly reflects, modifies or supplement Article 30 (2) of VCLT stating that *"[w]hen a treaty specifies that it is subject to, or that is not to be considered as incompatible with an earlier or later treaty, the provisions of that other treaty prevail."*

77. See, furthermore, section 6.5 below.

78. See section 6.2 above.

"instrument" also covers arrangements that are not legally binding.[79]

6.5. Pathogens

Article 4.3 on the relationship with international agreements and instruments contains an unusual provision. In connection with the Protocol's implementation, it states that due regard has to be paid "*to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.*" This provision is unusual because it contains an obligation to take into consideration "*useful and relevant ongoing work or practices*," when implementing the Protocol's legally binding obligations. The provision reflects the disagreement between industrialized and developing countries on the issue of pathogens. Besides, the Commission's Report does not provide further clarifications on this provision.

Pathogens are disease-causing agents. They can be bacteria, parasites, prions or viruses and they are covered by the CBD definition of genetic resource. Research on pathogens is important for developing medicinal drugs and for combating and curing diseases. This is why pathogens are economically important for the pharmaceutical industry, not least in the context of pandemics where the development and patenting of vaccines is common practice.

The problem underlying the controversy on pathogens—and thus also the relationship between the Protocol and the WHO—derives, in particular, from the disagreement between the EU and certain developing countries on the legal status of pathogens within the WHO. This disagreement concerns benefit-sharing when developing countries make viruses available to the WHO, the terms for patenting the resulting vaccines,[80] and the extent to which the rules of the Protocol should apply to pathogens. Formally, pathogens are covered by the Protocol. However, in the preamble there is a reference to being "*mindful of*" the WHO "*International Health Regulations (2005) and the importance of ensuring access to human pathogens for public health preparedness*," which is given much weight in the Commission's report.[81] In particular, the latter notes that even though the Protocol covers pathogens, the reference to the "*ongoing work*" in Article 4.3 does not prejudge the WHO negotiations on "Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits." In May 2011 a Pandemic Influenza Preparedness (PIP) Framework (Agreement) for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP Framework) was adopted by the WHO Assembly at its 64th meeting in the format of two resolutions.[82] Whether the resolutions may be considered as instruments under Article 4 (4) of the Protocol is at least doubtful.[83] On the other hand, they may qualify as useful and relevant practices under relevant international organizations as provided for in Article 4 (3). Furthermore, Parties may take the resolutions into consideration by virtue of Article 8 (b) on cases of present or imminent emergencies.[84]

According to the EU Commission, Article 8(b) indicates that benefit-sharing from pathogens has to be treated in a special way, meaning that it needs to be treated—more or less implicitly—under the auspices of the WHO, which is not an obvious conclusion.[85] Maybe a solution in respect of pandemic influenza pathogens has been found, but the treatment of other pathogens is probably going to remain a controversial issue in terms of the applicable ABS regulatory framework.

6.6. Research, in particular, non-commercial research

The Commission's report states that Article 8(a) on the promotion of research, including through simplified measures for non-commercial research,

79. On the one hand the fact that the term is commonly applied to cover also non-legally binding instruments, e.g. resolutions or decisions by international organizations or COPs, and that Article 4 in other provisions applies the term "international agreements," might indicate that the term also includes non-legally binding instruments. On the other hand the way in which the term "international instrument" is applied in Article 4 (3) as referred to above points at instruments which are legally binding. See, furthermore, section 6.5 below.

80. A thorough account of this is found in *Elisa Morgera and Elsa Tsioumani (2010)* (*supra* note 42) at p. 169. See also *Intellectual Property Watch*, Vol. 7, No. 12/Vol. 8, No. 1 (2010/2011), at p. 3.

81. On the WHO International Health Regulations, see Janne Rothmar Herrman (2010), "Pandemisk influenza – de retlige rammer for forebyggelse og bekæmpelse af epidemiske sygdomme" (on pandemic flue and the legal framework for preventing and combating of epidemics), *Juristen*, at p. 78.

82. *WHO Res. A 64/8* of 5 May 2011 and *WHO Res. A 64/5* of 24 May 2011.

83. See section 6.4 above.

84. See section 5 above.

85. See, equally, Gurdial Singh Nihar (2011 c), "The Nagoya Protocol and Pathogens", *South Centre Policy Brief 4*, 2011, who is more critical to the conclusion of the EU Commission, and also is questioning the conclusions of the Commission as related to Article 4(3).

fully meets the EU's requirements in this respect.[86] However, regulating the possible change of use from non-commercial to commercial research is a challenge, which is difficult to solve in advance. Detailed provisions in MAT on obligations to negotiate and agree on a new contract, if the purpose of the research changes during the course of it, might solve the problem. However, the question of what exactly is meant by "simplified measures" is also outstanding.[87]

6.7. The relationship between the Protocol and patent law

During ABS negotiations, a controversial issue was the relationship between the Protocol and patent law, in connection with the possible introduction of disclosure requirements in patent applications for both TK and genetic resources. In this respect, developing countries' requests were largely ignored. Intellectual property rights are only mentioned once in Protocol, namely in the Annex, which provides a list of possible monetary and non-monetary benefits. In addition, the demand of the developing countries to include explicit reference to patent authorities as possible checkpoints was not met.[88] With the adoption of the Protocol by consensus, developing countries eventually came to terms with the inclusion of less prescriptive obligations in terms of monitoring and tracking the use of genetic resources. The above demands of the developing countries have to be seen in light of their position within World Trade Organization (WTO), which postulates that the TRIPs Agreement[89] should contain the requirement that the patent application (for an invention based on genetic resources and TK) shall provide information on the origin of these resources and TK.[90] This is also discussed in WIPO,[91] which is the *forum* preferred by the EU for discussing the protection of TK while the EU has accepted to discuss the issue of disclosure in the TRIPs Council.[92]

The Commission's report concludes that since there are no obligations to use patent authorities as checkpoints, the Protocol does not prejudge the result of the negotiations in WTO and WIPO on this issue. An almost direct link between the issue of checkpoints and patent authorities is, however, established by the COP decision related to first review of the Protocol.[93] According to the decision[94] the first review "*shall assess the implementation of Article 16 in light of development in other relevant international organizations, including, inter alia, the World Property Organization*".[95] Article 16 is dealing with compliance and Article 17 with measures to support compliance.[96] Hence, the door seems to have been kept open for coming back to patent authorities as checkpoints.

6.8. Internationally recognized certificate of compliance

The EU Commission's report on the Protocol concludes that the latter does not require that

86. The rules of CBD also require PIC in order to gain access to genetic resources for non-commercial research, see sections 2 and 6.3 above. A cautious guess is that while the relevant Danish industries have been familiar with these rules since a long time, e.g. Novo Nordisk guiding principles available at http://www.novonordisk.com/Reports/press/environmental/er97/bio/Guidingprinciple.html, basic research under the auspices of universities generally has not.

87. The comments to Article 16 in *Informal Expert Consultation (2011)* (*supra* note 37) points to the fact that research is almost always based on cooperation. Hence, it is a challenge to enforce the terms of a research-based access to genetic resources.

88. Cf. Article 17. *Supra* note 65.

89. WTO Agreement on Trade-related Aspects of Intellectual Property Rights.

90. *Document TN/C/W/59 of 19 April 2011* containing a proposal of developing countries from Asia, Latin America and African Caribbean and Pacific countries group containing a draft decision on mandatory disclosure provisions. On disclosure and TRIPs, see also *E. Morgera and E. Tsioumani* (2009), (*supra* note 44), pp. 168.

91. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) established by the General Assembly of the World Intellectual Property Organization (WIPO) in October 2000 (see section 4.4 above) decided at its 19th session in July 2011 to recommend to the General Assembly to require the IGC to expedite its work on text based negotiation aiming at reaching agreements on a text(s) of an international legal instrument(s) ensuring effective protection of genetic resources, traditional knowledge and cultural expressions. See *WIPO/GRTKF/IC/19/REF/DECISIONS* available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=175487, and *Elisa Morgera* (2011), (*supra* note 53).

92. See *Communication of the 23rd December 2003 from the Commission to the European Parliament and the Council on the Bonn Guidelines* (COM (2003) 821 final), at pp. 18.

93. Article 31 provides for an evaluation of the effectiveness of the Protocol by the COP-MOP at intervals determined by the COP-MOP. The first review, however, shall be undertaken four years after the entry into force of the Protocol.

94. *COP Decision X/1*, para. 6.

95. *COP Decision X/1* includes the proviso that developments in other international organizations to be taken into consideration *"do not run counter to the objectives of the Convention and the Protocol"*. Hence, the language comes close to what is provided for in Article 4 (3) on ongoing work or practices, see section 6.4 above. The difference, however, is that Article 4 concerns obligations of Parties while the COP decision is addressing the COP-MOP.

96. See section 5 above and section 6.8 below.

all genetic resources used in a Party have to be accompanied by the internationally recognized certificate of compliance in accordance with Article 17(3). It also concludes that this is in line with the negotiation position of the EU.[97] The scope of this statement is unclear. Genetic resources which have been acquired from a Party to the Protocol after the entry into force of the Protocol are, in all circumstances, subject to the requirements of Article 17 (3).[98] However, since the EU Commission has argued that the Protocol only covers such resources the statement seems to be somewhat circular.

7. THE NAGOYA PROTOCOL AND DENMARK: LEGAL AND POLICY PERSPECTIVES

7.1. Introduction

The CBD and the Protocol are international treaties. They regulate the relationship between sovereign states and not between private actors or between private actors and states. The latter are regulated by the measures that state Parties will have to implement in order to comply with their mutual obligations and to protect the rights that these obligations reflect. On this basis, there are two main questions in relation to Danish law. First, the question of rights, *i.e.* the right to regulate access to Danish genetic resources and the subsequent right to benefit-sharing. Second, the question of obligations, *i.e.* the obligations to implement the rights that other Parties have under the Protocol, in particular, concerning the compliance of users with domestic ABS legislation or regulatory requirements.

7.2. Denmark as provider country

CBD Article 15 demands PIC in order to obtain access to genetic resources that are found in other Parties, unless the concerned Party decides otherwise. The Danish ratification of the CBD was based on a governmental motion that was ratified by the Danish Parliament. In the motion's section on Denmark's fulfilment of its obligations under the Convention, it is stated that: "*[t]he ascertainment that the principle of 'prior informed consent' in general does not apply to the exportation of genetic resources from Denmark, and that there does not – for the time being – seem to be a need for such rules, must be regarded as adequate for meeting the demand of Article 15(5) of the Convention that a decision has to be made not to use prior informed consent.*"[99]

Denmark may possibly confirm the decision not to require PIC from users who wish to access its genetic resources, since the provisions of the Protocol does not require a Party to introduce PIC[100] and Article 6 (1) of the Protocol encapsulates the principle of CBD Article 15 (4),[101] i.e. that PIC is required unless otherwise determined by the Party.[102] However, a renunciation of exercising its sovereignty in that respect has to be viewed in light of the perception that the Danish nature is quite poor in terms of biodiversity. It should not be interpreted as a reminiscence of the idealism of former times according to which genetic resources should be considered humanity's common heritage.[103]

97. See section 5 above.

98. Provided, by virtue of Article 17 (2), that a permit or its equivalent (as evidence of the decision to grant PIC and of the establishment of MAT) has been issued in accordance with Article 6 (3) (e) and made available to the Access and Benefit-sharing Clearing-House (see section 5). According to M. *Buck and C. Hamilton* (2011), (*supra* note 18), at p. 54, it is unclear whether it is the act of registration in the ABS Clearing-House which entails that a domestic permit obtains the status of an internationally recognized certificate of compliance under Article 17 (3), or whether the registered information itself constitutes such certificate.

99. Motion no. B, Folketingstidende (the Danish Parliament Herald) 1992-93, 2. Session, Addendum A 8600, B 1243 and FF 6581, 7806 and 7945. According to *Nordic Council of Ministers (2003)*, (*supra* note 73), at p. 93 this means that Denmark has not yet decided whether access to its genetic resources will be regulated through a PIC-like mechanism in the long term.

100. Obviously, Danish legislation relating to protection of species of wild fauna and flora would still have to be respected, including e.g. prohibitions of collecting specimens of wild fauna and flora in certain protected areas.

101. See section 2 above.

102. Whether a renunciation of the right to require PIC entails an obligation to inform the Access and Benefit-Sharing House accordingly is somewhat doubtful. It may be argued that such determination is, at least indirectly, a measure on access, thus being subject to the requirement of Article 14 (2) (a) to inform the Clearing-House on, *inter alia*, legislative, administrative and policy measures on access. It is equally information relevant to the implementation of the Protocol; cf. Article 14 (1). In any event, lack of such information would entail legal uncertainty, because lack of information on ABS-legislation of a specific Party at least for some years after the entry into force of the Protocol might indicate that the Party is not yet in compliance with its obligations under Article 6 (3), rather than it has waived its right to require PIC; cf. in this respect section 8 below on ratification of international treaties by developing countries. It is quite obvious that the above issue should be addressed and clarified as quickly as possible by a decision of the COP-MOP, since Parties shall under Article 14 (2) also make available to the Clearing-House information required pursuant to such decision.

103. See *Veit Koester* (1996), (*supra* note 9), at p. 275, *E. Morgera and E. Tsioumani* (2010), (*supra* note 44), at p. 152, and section 8 below at note 123.

In this respect, Denmark is probably in line with most other industrialized countries.[104] The fact that Denmark some twenty years ago decided not to require PIC for access to genetic resources does not prevent Denmark from introducing a PIC-requirement, e.g. in connection with a decision to become Party to the Protocol. Neither is Denmark prevented from determining that access to specific genetic resources requires PIC, while access to other genetic resources is unregulated, or that only access to genetic resources in specific areas in Denmark requires PIC. The issue of requiring PIC is not a question of either a PIC-requirement or no PIC-requirement. States have sovereign rights over their natural resources and, hence, the authority to determine access to genetic resources.[105] Leaving aside the issue of the rights of ILC neither the CBD nor the Protocol, however, is interfering with the relationship between a state and its citizens. To what extent a state may regulate access to genetic resources with legal effects vis-à-vis its citizens depends on domestic legislation, being basically an issue of property rights over biological resources.[106]

7.3. Current legal situation

Currently there are no rules in Denmark regulating access to and utilization of Danish genetic resources (with the exception of the indirect limitations that may derive from property law, exclusive rights that may follow from intellectual property legislation, and from contract-based rights). Because there are no general provisions in Danish law that establish rights to genetic resources, the situation is that those who hold rights or actual control over a biological resource are also entitled to utilize the genetic resources contained therein.[107] However, this issue may require further analysis, which exceeds the scope of this article.[108] The existing rules for granting access to biological resources that may belong to third parties should also be further considered.

Which implications do the right to harmless consumption that is based on the "Danske Lov" (i.e. The Danish Law of King Christian V) and its subsequent implementation may have regarding the rules on access to nature and biological resources?[109] Property rights over biological resources do not provide for the exclusive access to, and control of, genetic resources since the owner, generally speaking, cannot prevent others having property rights over the same kind of biological resources from access to and control of the genetic resources. However, they may provide for the owner an actual or *de facto* control over them. In this context the question may be raised whether this control is limited by the "Danske Lov" 6-17-31. One may argue that the utilization of the biological resources is usually harmless, since it neither damages the property nor it depletes the resources. If genetic resources, however, are utilized in the sense of the Protocol[110] and this leads to a patentable invention the landowner's property is damaged by being cut off from

104. Australia is one of the few exceptions, see *Supra* note 15. According to survey of European countries in Jorge Cabrera Medaglia *et al.* (2011), *Overview of National and Regional Measures on Access to Genetic Resources and Benefit-Sharing: Challenges and Opportunities in Implementing the Nagoya Protocol. First Edition,* Centre for International Sustainable Development Law (CISDL), McGill University, Canada, at pp. 53, hardly any EU member state has proper PIC legislation. No PIC legislation does not, however, necessarily mean the same as a renunciation – even *de facto* – of requiring PIC, and lack of PIC legislation in industrialized countries should probably also be viewed in light of the years of general opposition from the industrialized countries towards a legally binding ABS-regime. Besides, it is most likely that industrialized countries' legislation on protected areas is regulating, at least indirectly, access to genetic resources in such areas. The fact, however, that there is no information available on PIC legislation of e.g. EU Member States clearly confirms that in general no such legislation exists.

105. Cf. CBD Article 15 and *E.C. Kamau et al.* (2011), (*supra* note 60), at p. 260.

106. The sovereign rights of states over "their natural resources" in Article 15 (1) of the CBD (and of para. 3 of the Preamble of the Protocol) is referring to natural resources under a state's jurisdiction. See Lyle Glowka, Francoise Burhenne-Guilmin and Hugh Synge in collaboration with Jeffrey A. McNeely and Lothar Gündling (1994), *"A Guide to the Convention on Biological Diversity"*, IUCN – The World Conservation Union 1994, at p. 76. See, furthermore, section 7.4 below.

107. This view is taken from M.W. Tvedt (2010), (*supra* note 8), at p. 53.

108. In *Nordic Council of Ministers* (2003), (*supra* note 73), at p. 93, it is simply stated that there are several laws that regulate the rights to biological materials and their use, which may have implications for access to genetic resources.

109. "Danske Lov" was issued in 1683 by the Danish King Christian V, and several provisions are still valid, e.g. the provision contained in "Danske Lov" 6-17-31, which stands for Book 6, Chapter 17, Article 31. This provision grants a right for everybody to collect as many nuts "as he can consume at once and no more." "Nuts" are interpreted also to include flowers, leaves, berries, fruits, fungi etc., and consumption should not be understood literally or as immediate consumption. This provision does not in itself provide a right to access properties, but the Danish Nature Protection Act grants the public access to nature in the countryside, i.e. to publicly owned land as well as privately owned forests, uncultivated fields, beaches, pathways, *etc.* "Danske Lov" 6-17-31 and other specific regulations based on it are applicable in all these respects, cf. Veit Koester (2009), *Kommenteret Naturbeskyttelseslov* (Commentary to the Danish Nature Protection Act), Jurist- og Økonomforbundets Forlag, at p. 569.

110. See section 4.2 above.

a similar utilization. However, this kind of argumentation is hardly tenable.

It is the role of natural sciences and of the relevant user communities to guide the Government and the Danish Parliament on whether the Protocol itself and/or other developments during the almost twenty years that have passed since the Danish renunciation of its rights to regulate access to Danish genetic resources provide good reasons for subjecting such access to PIC. Other considerations may also be relevant, e.g. if countries with similar ecosystems and habitats as those existing in Denmark are introducing ABS-legislation.

7.4. Legal considerations

There is probably no doubt that introducing PIC for access to Danish genetic resources would not as such be in conflict with domestic legislation.[111] In any event, a conflict would not arise if those having property rights over the biological resources or being owners of the land where the resources exist remain in control of access to the resources. It seems reasonable, however, to rule out in beforehand PIC-requirements in respect of domesticated or cultivated species, because Denmark, in the sense of the Protocol, is not the country of origin of a number of or maybe the majority of these species.[112] Moreover, they are, generally speaking, subject to property rights.[113] In addition, utilization of genetic resources of such species, e.g. for breeding or propagation, may be subject to exclusive rights. Thus, PIC-requirements should be limited to genetic resources of species that are not cultivated or domesticated. It is, however, difficult to imagine a regulation of access to Danish genetic resources without simultaneously taking a stand on the general rules that should apply for genetic resources.

In Norway, the deliberation and implementation of this sort of general rules took a number of years. The central provision on this is the Norwegian Nature Diversity Act ("*Naturmangfoldloven*") and, in particular, Article 57, which states: "*Genetic material from nature is a common resource, which belongs to the community of Norway and is managed by the state. The utilization has to be as beneficial as possible for the environment and humanity in both a national and international perspective, with emphasis on an appropriate sharing of the benefits arising from the utilization of genetic resources in such a way that the interests of indigenous and local peoples are looked after. The first section does not limit the right that an owner or other legitimately has to refuse access on another basis a) to the biological material, or b) to the land from where the genetic material is taken.*"[114]

The comments to the above provision state that the expression "from nature" means that the concerned genetic material has to belong to naturally wild species, thus excluding organisms influenced by man through cultivation and breeding. Article 57 of the Norwegian Nature Diversity Act is supplemented by special provisions on marine genetic material in the Act on Marine Resources, which in some respects are more comprehensive than the former.[115]

Article 57 of the Norwegian Nature Diversity Act is supplemented by Article 58, which grants the minister for the environment competence, subject to reservations similar to those of Article 57 above, to lay down the rules concerning the taking ("uttak") of biological material from nature "*in order to utilize the genetic material, or that utilization of such material requires a permit. If a permit to the taking of biological material has been issued a permit for a subsequent utilization is not required.*" Furthermore, rules can be enacted, *inter alia*, to provide that the benefits arising from the utilization of genetic material be allocated to the state. This authorization has not yet been used.[116] The

111. Conflict with domestic legislation in the above connection means conflict with the provisions of Article 73 of the Danish Constitution protecting property rights. Internationally, property rights are also protected by various human rights treaties, e.g. Art. 1 of Protocol No. 1 to the European Convention on Human Rights. Moreover, "*taking into account all rights over* [genetic] *resources*" is also, similar to CBD Article 1, included in Article 1 on the objective of the Protocol.

112. See, furthermore, section 6.2 above, *inter alia*, on the FAO Treaty.

113. See section 7.3 above. On the one hand, a refusal of PIC for access to specific genetic resources of domesticated or cultivated species might interfere with property rights, thus contravening domestic legislation (*supra* note 111). On the other hand, would PIC in the form of a pure formal requirement, i.e. without any substantive content, hardly be sensible.

114. A committee ("Biomangfoldlovudvalget"), which worked on the Norwegian Nature Diversity Act from 2001 to 2004, suggested the following provision on genetic material: "*Within the boundaries of this law and other legal rules anyone has the right to search for, take out and utilize genetic material. This right does not limit the right that an owner or other legitimately has to refuse access on another basis a) to the biological material, b) to the land from which the material is taken*." This suggestion, however, was not followed when the bill that was proposed and passed 5 years later. See *M.V. Tvedt* (2010), (*supra* note 8), at pp. 94.

115. See respectively Act No. 100 of 19 June 2009 on the preservation of nature, landscape and biological diversity (the Nature Diversity Law) and Act No. 37 of 6 June 2008 on the management of wild marine resources. For a survey of the Norwegian ABS legislation, see *Jorge Cabrera Medaglia et al.* (2011), (*supra* note 104), at pp. 57.

116. Supposedly, the Norwegian rules of the above Articles 57 and 58 entail some problems of interpretation, e.g.

question arises whether ABS rules, seen from the perspective of Denmark as a provider country, may be drafted on basis of, or by drawing on inspiration from, the above Norwegian provisions. Basically, this is a political issue. From a legal point of view, various avenues might be considered.

A rather wide approach would be establishment of property rights of the Danish State over genetic resources of species of wild animals and plants[117] along the lines or principles of the Act of the Subsoil.[118] Species of wild animals and plants is a rather well defined concept in existing Danish legislation,[119] and some species are legally protected.[120] Establishing property rights over genetic resources of wild fauna and flora would entail only that the rights to utilize such resources as defined by the Protocol[121] would rest with the Danish State. Such rights would not interfere with existing legal rights of landowners to use these biological resources in other ways, e.g. for hunting purposes or as food or feed.

It would, however, be necessary to introduce a reservation in line with the above Article 57 of the Norwegian Nature Diversity Law to the effect that state property rights do not limit the rights that a landowner legitimately has to refuse access to the biological resources or to the land where they occur. To what extent state property rights should include genetic resources accessed prior to the establishment of those rights, including genetic resources in *ex situ* collections, would need further consideration. *Ex situ* collections, however, are predominately to be found in the public domain.

The application of state property rights would have to comply with the requirements of Article 6 (3) of the Protocol.[122] The Ministry of Environment, being generally in charge of wild fauna and flora, would be the most appropriate competent authority, also in respect of the establishment of MAT. An additional decision would be needed in order to fulfill the requirement of Article 9 to direct benefits arising from the utilization of genetic resources towards conservation of biological diversity and the sustainable use of its components. Equally, the issue of benefit-sharing would need further consideration, since Article 5 (1) requires that "*benefits arising from the utilization of genetic resources … shall be shared in a fair and equitable way with the Party providing such resources*." On the other hand, benefit-sharing does seem, at first glance, to be relevant only as far as benefit-sharing with the Danish State is concerned. Furthermore, the Protocol offers in that respect a large degree of flexibility as demonstrated by the non-exhaustive annex to Protocol on monetary and non-monetary benefits. Moreover, it would hardly be possible to question that benefits, deemed by the Danish State to be fair and equitable, do not correspond to the requirements of Article 5 (1). And who might at all be entitled to do so?

A principle of state property rights over genetic resources might be established with a coverage including the land territory and territorial sea of Denmark as well as the exclusive economic zone,[123] or parts of these areas, e.g. only marine areas or only protected (land or marine) areas,[124] pending, *inter alia*, on a mixture of scientific, technical, technological, administrative, financial and legal considerations.

related to the concept of "common resource" which is a new concept in Norwegian law and not defined by the Act. In addition, there may also be problems concerning enforcement. However, these questions will not be dealt with any further in this article. See *M.W. Tvedt* (2010), (*supra* note 8), pp. 89-120.

117. According to an article in the Danish newspaper "Politiken" of 4 December 2011 a project with a view of DNA barcoding of the 1400-1600 Danish species of wild plants is currently under preparation. Such coding might facilitate enforcement of PIC requirements.

118. Article 2; cf. Article 1 of Consolidated Act No. 960 of 13 September 2011, according to which raw materials in the Danish subsoil, including the subsoil in the Danish Economic Zone and Continental Shelf, that have not been subjected to private economic exploitation prior to 23 February 1932 (dating from the first Act) are owned by the Danish State.

119. It might, however, be doubtful whether or to what extent the concept, e.g. as incorporated in the Danish Nature Protection Act, includes micro-organisms. Neither are such organisms included in the Habitat Directive, see *infra* note 120.

120. Including those which are protected under *Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (codified version),* O.J. L 20/07 (Bird Conservation Directive), and *Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora,* O.J. L 206/07 (Habitat Directive).

121. See section 4.2 above.

122. See section 5 above.

123. As far as the continental shelf beyond the economic zone is concerned, Article 82 of the Convention on the Law of Sea (UNCLOS), see section 6.2 above, contains obligations to share with the international community part of the revenue from the exploitation of the resources.

124. E.g. Special Protected Areas (SPAs) under the Bird Conservation Directive and Special Areas of Conservation (SACs) under the Habitat Directive (*supra* note 64) as well as other areas protected under the Danish Nature Protection Act.

7.5. Some conclusions

State property rights were rejected in Norway. However, why the establishment of state property rights would present decisive or insurmountable obstacles, including in respect of their enforcement, is difficult to understand. This issue, however, would have to be analyzed more thoroughly, in particular whether such rights could be managed under the observance of roughly the same considerations of the Norwegian Nature Diversity Act. It also needs to be considered whether derivatives should be covered, since a state has the right to control access to and utilization of these, regardless that the Protocol may not cover access to derivatives.[125] In some countries with ABS legislation, the relationship between such legislation and property rights is unresolved, whereas in some South American countries genetic resources are viewed as *dominio publico*, that is, something that is non-transferable, non-disposable and cannot be subjected to private property.[126]

However, the decisive factor, in particular, from the Danish perspective, is going to be the delimitation and the enforcement of domestic ABS legislation and regulatory requirements both nationally and internationally.[127] The final decision will most likely imply a variety of considerations ranging from scientific, technical and technological considerations to considerations of a legal, administrative and financial nature. Potential outcries from educational and research communities in case of regulation of access to genetic resources and benefit-sharing might be smothered with a flexible permit or authorization system in line with the requirements of Article 8(a) of the Protocol.[128] It can be a central question whether it is worth at all the effort to legislate on ABS rules more precisely. However, nobody may know, for instance, which species of interesting organisms may be found in or on the seabed of marine areas over which Denmark has sovereign or economic rights.[129] And would it preferable to leave these resources freely accessible, even if that means that there will be no certainty on whether any benefits would actually accrue to Denmark? These questions may have important implication both from an innovations perspective that focus on private economic dimensions and for the Danish society as a whole.

7.6. The Faroe Islands and Greenland

The Faroe Islands and Greenland are parts of the Kingdom of Denmark, both of them, however, with home rule competences, and none of them included in the Danish membership of the EU. Since the Protocol according to Article 34 does not provide for any reservations to be made, a Danish consent to be bound by the Protocol[130] would, formally speaking, need to include the Faroe Islands and Greenland. Presumably, some other industrialized countries would have to consider issues of a similar nature, which, of course, do not entail any problems when legislation and other measures enabling such parts of the States to implement the Protocol are in place.

As far as Greenland is concerned, the Parliament of Greenland in 2003 enacted specific provisions on genetic resources. The basic provisions are found in Article 37 in the Act of Parliament ("*Landstingslov*") no. 29 of 18 December 2003 on Nature Protection. [131] The provisions of Article 37 and of

125. See section 4.3 above.

126. See *M.W. Tvedt* (2010), (*supra* note 8), at p. 94.

127. The Norwegian delimitation of possible ABS measures, which may apply to genetic resources "from nature," would probably cause greater problems in Denmark than in Norway, even though it actually (only) covers wild animals and plants (and other organisms) that are not affected by humans through cultivation and breeding, and that term "nature" is widely applied by Danish legislation, e.g. by the Danish Nature Protection Act.

128. See section 5 above.

129. See, e.g. Lyle Glowka (1996), The Deepest of Ironies: Genetic Resources, Marine Scientific Research, and the Area, Ocean Yearbook, Vol. 12, pp. 154-178, which, however, is dealing with genetic resources in or on "The Area" (see section 6.2 above).

130. I.e. according to Article 33 of the Protocol by an instrument of ratification, acceptance, approval or accession.

131. Article 37 states: "(1) The acquisition, taking or use of Greenlandic genetic resources, including parts of the resources, or the export of such resources or parts thereof from Greenland shall not be permitted unless the permission of the Cabinet has been obtained. (2) The provision of subsection (1) hereof shall not comprise any acquisition, taking, use or export that is in compliance with the other provisions of this Act and which takes place (1) with a view to direct use or consumption, including in a processed state and for commercial purposes; (2) for non-commercial private and personal purposes. (3) A permission under subsection (1) hereof may impose such conditions as are found to be necessary to ensure that a reasonable share of the profit from exploitation for research and commercial purposes of the resources mentioned in subsection (1) hereof accrues to the Greenlandic community, including possibly the particularly affected local communities. (4) The Cabinet may lay down rules concerning investigation and exploitation of Greenland's genetic resources".
The author of the present paper accepts the responsibility for some of the criticisms, which may bee levelled at the provision. In 2001, the author was sent to Greenland by the then Minister for the Environment (the late Mr

the Supplementary Act No. 20 of 11 November 2006 on the *Utilization of Biological Resources for Commercialization and Research* could be already adequate to implement to the Nagoya Protocol's requirements regarding the ABS legislation that Greenland needs to enact as a provider county or as the country of origin. However, ABS legislation in these respects does not satisfy the requirements of the Protocol. Also user measures are needed, at least formally speaking, and no such measures are presently available. Altogether any Party can be both a user country in one occasion and a country of origin in another.

Apparently no ABS legislation exists as far as the Faroe Islands are concerned, neither from the point of view of the Faroe Islands as a provider country, nor as a user country.

The issue of the Faroe Island and Greenland has to be resolved by negotiations of the Danish Government with the Home Rules of the Faroe Islands and Greenland, and by the assessment of the latter of the implications of the Protocol. Thus, the Home Rule of the Faroe Islands would have to take into account that requirements on users to obtain PIC according to Article 6 (1) flow from the domestic law of the provider country, and – not as before – directly from the CBD. Theoretically, it may be possible to resolve the "user country issue" by means of suitable declaration by the Danish Government to the effect that neither the Faroe Islands nor Greenland are likely to become user countries in a foreseeable future.

7.7. Denmark as user country

As above mentioned, the Protocol contains obligations to implement measures to ensure that the requirements concerning PIC and MAT are respected by users. These obligations are to be found primarily in Articles 15 to 18.[132] There is no doubt that these obligations cannot be met within the framework of the existing Danish legislation.

Articles 15 and 16 do not necessarily require the enactment of binding rules since the required measures can also be "policy measures" (i.e., *inter alia*, guidelines) under the condition that they are effective and "proportionate." This topic, however, will be part of the preparation for the first Meeting of the Parties to the Protocol (COP-MOP) and quite possibly it will focus on existing guidelines with international dimensions.[133]

The implementation of Article 17 on the designation of checkpoints and the determination of their role can hardly undertaken without the adoption of binding rules in these regards. Whether parliamentary legislation is required probably depends on the characteristics of the checkpoints. The requirements of Article 17 that users of genetic resources have to provide information on PIC, the origin of the genetic resources and MAT to checkpoints might require the authorisation of the legislator, in accordance with the rule of law, and must be implemented in the form of binding rules.

Relevant checkpoints are, *inter alia*, authorities granting permission to – or carrying out assessments with a view to – marketing new products and could be public research institutions. In Denmark, such checkpoints might be established under the Danish Veterinary and Food Administration, the Danish Medicines Agency and the Danish Plant Directorate. However, the issue has also to be considered in light of the forthcoming EU legal and policy framework. For example, the European Food Safety Authority (EFSA) and the European Patent Office, and maybe the Community Plant Variety Office (CPVO), could be designated as checkpoints. On the other hand, the Danish Nature Agency could perform the functions of "national focal point" and/or "national authority."[134] In Denmark, there is already an institution, which performs some checkpoint's functions, namely the Danish Patent and Trademark Office. This is because Denmark is one of the very few industrialized countries – maybe the first ever – that in 2000 implemented disclosure of origin requirements. In other words, patent applications concerning an invention, which is based on or utilises biological materials of vegetable or animal origin, shall contain information on the materials' geographic origin. Besides, if the applicant does not know the origin of the material, this must be stated in the application. However, the lack of information concerning the geographic origin or the material neither affects the processing of the application nor the granting and enforcement of patents rights.[135]

Sven Auken) to aid the Greenlandic authorities with the elaboration of a new nature protection act, because of criticism – especially from abroad – on aspects of previous nature management measures in Greenland. The author used this opportunity to suggest that the new law should contain provisions on genetic resources and their developed, and made a proposal for this. The basic elements of the above quoted provisions stem from such proposal.

132. See section 5 above.

133. In connection to the first meeting of the the Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol on ABS (cf. section 6.2 above) the EU has pointed to a number of existing codes of conduct and the like including, inter alia, guidelines on ABS for members of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

134. Cf. Article 13.

135. The rule, which is now found in Article 3(4) of

The fulfilment of the Protocol obligations concerning private law enforcement of the mutually agreed terms in accordance with Article 18(2)[136] seems to be a complex issue that would require further analysis.[137]

7.8. Denmark as Member State of the EU

The Commission's report on the Protocol states *that* a ratification of the Protocol will most likely require new union politics or new EU-legislation,[138] *that* the Commission will carry out an analysis with public consultation during 2011 and consider to submit proposals on implementation measures in 2012, *that* there might be a need to supplement EU legislation with national measures in order to fully implement the Protocol, and *that* the ratification of the Protocol by EU and its Member States thus has to be viewed as a common undertaking.

The Commission has, furthermore, in a note of 6 October 2011, made a statement to the effect, *inter alia*, that given the extent of EU legislation that would be affected it is excluded that individual Member States would ratify unilaterally, prior to a ratification by the EU. Unilateral ratifications would be in conflict with the EU Treaty.[139] This seems to be a rather doubtful statement, since it also appears from the note that the Union has not adopted specific legislation on ABS. Moreover, the Commission never argued that the Bonn Guidelines[140] had an impact on EU legislation. Neither was apparently during the negotiation of the Protocol efforts made to align the provisions of the Protocol with existing EU legislation.

The Commission also observes that if the entry into force of the Protocol were to happen without the EU having ratified the EU would not be a Party at the negotiating table leading, possibly, to

regulation No. 93 of 29 January 2009 on patents and supplementing protection certificates is based on recital 27 of European Parliament and Council Directive 98/44 on Legal Protection of Biotechnological Inventions, but it differs from this, because the "should" in the recital has become a requirement in the Danish Regulation. Provision of false or deliberately wrong information may be sanctioned under the General Civil Penal Code (see *A. T. Gebreselassie* (2012), (*supra* note 23), at pp. 229). The idea of "disclosure of origin" in patent applications as a means to control that the PIC demand of CBD is met was likely launched for the first time in *F. Hendrickx, V. Koester and Chr. Prip* (1993), (*supra* note 20), at p. 250, cf. the same authors in (eds. Vicente Sánchez and Calestous Juma) (1994): *Biodiplomacy. Genetic Resources and International Relations*, ACTS Press, Nairobi, at p. 148. The authors also suggest (at pp. 147) the enactment of a legal obligation of corporations *etc.* to keep a register of genetic resources which they hold for research and development purposes, to be open for inspection by the competent authority. According to *A. T. Gebreselassie* (2012), (*supra* note 23), at p. 230, the disclosure requirement of the geographic origin of the variety in Article 50 (1)(g) of Council Regulation 2100/94 on Community Plant Variety Rights is not important seen in an ABS perspective since the provision does not require disclosure of the origin of the parental plant. An elaborate provision on disclosure is found in the Norwegian Patent Legislation. This rule is analysed in *M.W. Tvedt* (2010), (*supra* note 8), at pp. 128, 138 and 149. Tvedt concludes that it is "an attempt at a somewhat well-guided punch straight out in the air" ("et forsøk på et noenlunde velrettet slag rett ut i løse luften"). Generally, it has to be recognized that this kind of rules are not very effective if they are not connected to the patentability of inventions. The developing countries are arguing in favour of establishing the above connection in WIPO and WTO, see section 6.7 above. The Norwegian Nature Diversity Law Article 60 contains a number of provisions constituting together with the above disclosure requirements in the Norwegian patent legislation and disclosure requirements in the legislation relating to plant breeder's rights, the ABS user-country measures of Norway. These measures are analysed in Morten W. Tvedt and Ole K. Fauchald (2011), "Implementing the Nagoya Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit Sharing in Norway", *The Journal of World Intellectual Property (2011)* Vol. 14, no. 5, pp. 383-402. The analysis concludes (at p. 398) that Norwegian legislation, in spite of the important and serious steps taken, is far from resolving all the issues necessary for creation of an effective benefit-sharing system. The article also concludes that when it comes to implementing ABS and the Protocol in a functional way "*it is clear that the legislature of one country, acting on its own, cannot resolve all the challenges relating to enforcement of ABS obligations towards users within its jurisdiction,*" and that coordination and cooperation with other user countries is needed.

136. See section 5.

137. See *M.W. Tvedt* (2010), (*supra* note 8), at pp. 153 on competence, *locus standi* and *locus fora*, etc. On certain problems of international law in that respect, see ibid. at pp. 125 and 160. See also *Claudio Chiarolla (2011),* (*supra* note 58), and the hypothetical case study in M.V. Tvedt and Ole K. Fauchald (2011), (*supra* note 135), at pp. 390. Whether the final result of the presently negotiating EU Draft agreement on a Unified Patent Court and draft Statute (http://www.eplawpatentblog.com/eplaw/2011/07/eu-draft-agreement-on-a-unified-patent-court-and-draft-statute-presidency-text.html) is going to facilitate enforcement or the opposite is a difficult issue which exceeds the scope of the present paper.

138. *Supra* note 63.

139. *Council of the European Union,* (15191/11) with an undated note from the Commission. The Commission also notes that, due to the timing of the EU legislative procedure, the EU would not be in a position to ratify the Protocol before late 2014. That would be too late for being a Party at any COP-MOP 1 of the Protocol back-to-back with COP 11 of CBD in 2012. It is, however, doubtful whether the requirements of Art. 33 (1) of the Protocol to the effect that it shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of consent to be bound by the Protocol is going to be met in time for COP-MOP 1. As per the 1st of January 2012 no states had ratified the Protocol according to the appropriate homepage http://www.cbd.int/abs/nagoya-protocol/signatories/ . See, furthermore, section 8 below.

140. See section 3 above.

certain decisions that might make it virtually impossible for the EU to ratify. Leaving aside that it is questionable whether the Protocol enters into force before COP 11 in 2012,[141] this statement is rather curious. First of all it is hardly conceivable that any such decisions would change or supplement fundamentally provisions of the Protocol. Second, decisions by the COP-MOP would not be legally binding, save perhaps at the internal level like e.g. rules of procedure or non-compliance procedures.[142] Third, it is not likely that the COP-MOP would ever take decisions while ignoring completely "objections" of a major stakeholder like the EU which, of course, would participate as an observer.[143]

So far, no analysis of existing EU legislation that may be affected by the implementation of the Protocol, and to what extent such implementation would be in conflict with EU legislation, is available. However, some of the basic elements of an international ABS regime were already in place some twenty years ago, e.g. the authority of national governments to determine access to genetic resources, access on mutually agreed terms, and PIC.[144] The Bonn Guidelines, adopted in 2002 with the active participation of the EU, contain a number of the elements or measures, relevant to both user and provider countries,[145] which are now included in the provisions of the Protocol. The Guidelines did not entail any real action from the side of the Commission vis-à-vis the Member States.[146] Hence, Member States might have implemented the Guidelines, had they wished to do so, which they, however, apparently did not. Furthermore, the EU was since 2004, similarly to a number of, but not all, Member States, a Contracting Party to a specialized international access and benefit-sharing instrument, namely the FAO Treaty.

It is obvious that EU legislation relating to intellectual property, e.g. protection of new varieties of plants, patenting, and biotechnological inventions, would have to be respected by Member States, but the provisions of the Protocol do not affect intellectual property rights, at least not directly. So, over and above, it is at first glance at least not obvious that existing EU legislation is likely to be affected in a way that would prevent implementation of the Protocol.[147] However, a thorough analysis may result in another conclusion.

As demonstrated above[148] the Protocol requires measures to be taken from the side of both provider and user countries. Those two sides are, of course, also relevant in an EU perspective. There is probably no doubt that EU Member States, including vis-à-vis the EU as such, have sovereign rights over their natural resources.[149] Accordingly, the right to determine access to genetic resources, and how as well as on which terms those resources

141. See *Supra* note 139.

142. The provision in Article 14 (2) to the effect that each Party shall make available to Access and Benefit-Sharing Clearing-House *"information required pursuant to the decisions taken by the"* COP-MOP should be seen as a procedural rule rather than a substantive obligation.

143. In addition, although the EU might from the entry into force of the Protocol be bound by previous decisions in a political sense, nothing would probably prevent the EU from making at the time of its ratification a declaration to the effect that it has reservations regarding specific decisions. Such declaration might entail a position of the EU similar to the position of Parties expressing a reservation to a decision being taken by a COP or COP-MOP, however, without having objected to the adoption of the decision by consensus. A reservation may, pending the circumstances and the content of the reservation, indicate that the Party is not going to comply with the decision.

144. CBD Article 15 (1), (4) and (5) respectively.

145. See section 3.

146. *Commission Communication of 23rd December 2003*, (*supra* note 92), presents a number of ideas, e.g. on informing users of their obligations, encouraging the disclosure of the country of origin in intellectual property rights applications, and development of voluntary certification schemes, but is to a wide extent referring to ongoing discussions in other fora and to various strategies and action plans, and does not contain any concrete actions, nor proposals for legally binding measures.

147. This finding is supported by the fact that the Commission Communication of 23rd December 2003, (*supra* note 92), in section 3 on EC legislation and policy measures on ABS is referring only to Directive 98/44 EC on Legal Protection of Biotechnological Inventions and Council Regulation 2100/94 on Community Plant Variety Rights, (*supra* note 135) mentioning, however, that EC regulations on the conservation and characterisation of plant genetic resources for food and agriculture "are also relevant".

148. See section 5 as well as sections 7.4 and 7.7.

149. The references in the Bird Conservation and Habitat Directives to some species of wild fauna and flora as "common heritage" or similar notions (see *Supra* note 120) do not change this conclusion, since they refer to biological and not to genetic resources as such. Furthermore, it may be argued that the mere fact of the existence of the directives underscores that Member States as a matter of principle have sovereign rights over their biological resources as well, not withstanding that the EU according to *E. C. Kamau et al.* (2011), (*supra* note 53), at pp. 261 has powers to set up its own research programs. Commission Communication of 23rd December 2003, (*supra* note 92), contains in section 6 inter alia the following statement: *"The need for actions at EC level aimed at harmonizing MS' legislation on access to genetic resources concerning stakeholders participation is not apparent and will have to be further assessed also on the basis of the experience gained with the implementation of the Bonn Guidelines. In principle, national access laws and participatory mechanisms are best suited to adapt to local realities and stakeholders' needs".*

may be utilized, rests with the Member States.[150] Nevertheless, the question may be posed whether similar provider-regimes in Member States would be required for reasons of competitiveness or enforcement. On the one hand it is not obvious why the fact that some genetic resources are under a PIC regime in one member state and not under such regime in another member state would inspire for instance a company to try to circumvent the regime of the former state by claiming that the genetic resource was accessed in the latter state. On the other hand, however, it cannot, however, be ruled out that some common rules, including a common format of the internationally recognized certificate of compliance,[151] might be beneficial to private stakeholders both within and outside the EU. Neither can it be excluded that uniform or harmonious user-systems in Member States might enhance compliance with ABS legislation of provider countries both within and outside the EU.[152] There might also be possibilities of designating some EU institutions as checkpoints.[153]

From a Danish perspective there is hardly any reason to await the abovementioned analysis of the EU Commission before thinking through some of the basic questions. It appears, *inter alia*, obvious to take immediately the first step towards a more thorough mapping of the legal status of genetic resources. The same applies to considerations of whether the fact that genetic resources in several respects seem almost to be *res nullius*, i.e. objects for free seizure, should also be the case in the long run. In this respect, as most likely in others too, time seems short.

8. CONCLUDING REMARKS AND KEY MESSAGES

Genetic resources are of paramount importance to mankind and possibly even to mankind's survival in the long run as a subject of research and development. Furthermore, the economic potential of these resources is enormous. The Protocol aims at filling the void that has existed for a long time concerning the legal protection of sovereign rights over genetic resources while also ensuring that the principle of facilitating access to the resources is safeguarded. The Protocol also aims at protecting the legitimate demands of the developing countries' indigenous and local communities of an equitable share of the benefits from the utilization of their resources, including traditional knowledge.

The above analysis[154] demonstrates that the provisions of the Protocol raise a number of interpretation problems. Equally, the analysis is questioning to some extent the implications of the Protocol as suggested by the European Commission.[155] None of the conclusions of the analysis, however, should be perceived as impediments to ratifying the Protocol, since most of the elements of the key provisions, e.g. Articles 5-7 and 15-18, seem to be sufficiently clear to be functional.

Most of the challenges are relating to the requirements of the provisions of the Protocol to domestic legislation and other measures on the domestic level, since ratification and implementation of the Protocol thus presuppose for most countries, not least the Western European States, legislation on and administrative regulation of an area, which has hitherto mostly been unregulated. This is a big challenge, and even more so as it is a legally complex area with many actors and diverse, sometimes conflicting, interests. The fact that the Protocol entails obligations under international law while also indirectly regulating issues under private law, including international private law, only accentuates this challenge. In addition to this is the EU perspective which is, of course, only relevant to industrialized countries being Member States of the EU.

As outlined above,[156] the European Commission had argued *inter alia* the following: 1) The Protocol is likely to require new EU policies or new EU legislation; 2) EU legislation would be affected by ratification of the Protocol, and 3) unilateral ratification would be in conflict with the EU Treaty. Although these allegations have not (yet) been substantiated by any kind of analyses and might be challenged,[157] it is obvious that Member States would have to consider carefully the views of the Commission. Moreover, it cannot, as argued above,[158] be ruled out that similar provider-regimes in Member States might be beneficial to private stakeholders, and that uniform user-systems

150. Member States are of course obliged to comply with the provisions of the directives referred to above when exercising their rights under any PIC arrangement. The directives, however, contain provisions according to which Member States may, under strictly supervised conditions, derogate from the provisions protecting the species, *inter alia*, for purposes of research.

151. See section 5 and section 6.8 above.

152. See section 7.7 above, especially *Supra* note 135 relating to the findings in *T.W. Tvedt and O.K. Fouchald* (2011).

153. See section 7.7 above. *Supra* note 53.

154. See section 4.

155. See section 6.

156. See section 7.8.

157. *Ibid.* From a user perspective, the competence basis for EU legislation on ABS is in *E.C. Kamau et al.* (2011), (*supra* note 53), at p. 261, characterized as "being weak".

158. *Ibid.*

might enhance compliance with ABS legislation of provider countries. This does not mean, however, that the above or similar issues necessarily need to be resolved before a ratification of the Protocol by Member States. Hence, Member States might ratify provided they are capable of implementing the Protocol from its entry into force. Ratification by Member States would not prevent the introduction, at a later stage, of EU legislation, as appropriate and in light of experience gained.[159] In any event, it would be regrettable if ratification by Member States would have to wait until late 2014 as indicated by the Commission,[160] or maybe even longer than that, since this would, from a political point of view, send a rather negative signal to developing countries.

Article 6 (1) of the Protocol confirms the principle of CBD Article 15 (5), i.e. that PIC is required unless otherwise determined by the Party.[161] Opposite to CBD Article 15 (5), however, Article 6 (3) of the Protocol is obliging a Party which has not made such determination to take a number of measures relating to PIC.[162] Hence, it is not possible to uphold the former "laissé-faire situation", i.e. on the one hand not to determine that PIC is not required, but on the other hand not to take the necessary regulatory measures. In reality, therefore, the Protocol presupposes an explicit decision on whether and to what extent to apply the principle of PIC for access to genetic resources. A decision not to require PIC, however, does probably not prevent the introduction of a legal requirement to notify the competent national authority before domestic genetic resources are being accessed and to inform the authority about the objectives of such access.

Probably, some EU Member States have not waived their right to require PIC under CBD Article 15 (5). Moreover, they have most likely not taken any measures to implement this right.[163] Being confronted with the requirements of the Protocol Member States now have to analyze the present legal status of their genetic resources, in particular in respect of existing property rights over biological resources, and which kind of legal regime should be applicable to the resources in the future, i.e. basically PIC or no PIC-requirements. Such decisions are EU Member States entitled to make, since they have, also vis-à-vis EU, sovereign rights over their genetic resources.[164] Relevant considerations are outlined above[165] with Denmark (including the Faroe Islands and Greenland) as an example and with Norway, being one of the very few industrialized countries with ABS-legislation, as a source of inspiration. For many Member States it is probably going to be rather difficult to arrive at a decision which is ultimately going to be based on a political choice. The decision involves a multitude of considerations, *inter alia*, of a scientific, technical, technological, administrative, financial and legal nature. Seen retrospectively, it is a pity that such considerations were not commenced years ago. The fact that the ABS issue was considered and negotiated internationally over almost the last twenty years did not prevent any determination of the legal status of a country's genetic resources, of PIC or no-PIC requirements, or of measures to implement such determination, since Article 15 of CBD explicitly recognize the sovereign rights to do so.[166]

159. The 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) entered into force on 1 July 1975. Leaving aside that the Convention did not originally allow the adherence of the EU (EEC), the provisions of the Convention were only taken over into Community law by a regulation adopted in 1982 (Regulation 3626/82, replaced, in 1997, by Regulation 338/97). An amendment of the Convention allowing the adherence of the EU was adopted in 1983, but has not yet been ratified by a sufficient number of contracting states. *G. Winter and E. C. Kamau* (2011), (*supra* note 33), seem to take the same position by stating, at p. 395, that "[s]ince the competence basis for EU legislation is problematic as long as it has not been made use of Member States would have to adopt their own legislation in order to promote their individual research and development activities" (author's translation).

160. See *Supra* note 139.

161. See section 2 above.

162. See section 5 above.

163. See section 7.3 above.

164. See section 7.8 above. *Commission Communication of 23rd December 2003*, (*supra* note 92), indicates in section 6 that Member States of the EC are providers of *in situ* genetic resources and also hold important *ex situ* collections, and that access to genetic resources in both cases "is regulated by a wide range of national laws."

165. See section 7.4 above.

166. It is, generally speaking, more easy and convenient for states to stick to their internationally recognized rights than to give up such rights. Hence, any common system regarding EU Member States in their capacity as provider countries would, if at all feasible, most likely be based on PIC-requirements. If PIC-requirements are going to be applied by Member States they might also in their mutual relationship take the role of being either provider or user countries. The fact that many species of wild fauna and flora occur in the whole EU region might need, at least for administrative reasons, a kind of common understanding on how to apply the requirements of Article 11 to endeavor to cooperate where the same genetic resources are found *in situ* within the territory of more than one Party. Seen in an idealistic perspective, however, it might be a rather attractive idea that EU Member States agree on the principle that genetic resources of their wild fauna and flora belong to the common heritage of humankind, i.e. being freely accessible. As far as Denmark is concerned it has not caused any problems that this has *de facto* hitherto been the case. Traits of the principle of common

The first Meeting of the Parties to the Protocol (COP-MOP 1) will take place in connection with the 11th Meeting of the Conference of the Parties to the CBD in October 2012, in Hyderabad, India.[167] Over and above it is rather doubtful whether it is possible to reach the necessary conclusions in time for that meeting. In this respect the potential need of approval of parliaments has to be taken into account as well as the potential need for new legislation. Supposedly, legislation is required in most EU Member States, as well as in many other industrialized countries, if they intend to formally introduce PIC-procedures.

The above first Meeting of the Parties to the Protocol (COP-MOP 1) will take place, only if the ratification status of the Protocol will have allowed its entry into force.

For this purpose, ratification is required by 50 states (or 49 states and the EU) plus the passing of three months since the 50th ratification.[168] The Cartagena Protocol on Biosafety (a protocol to the CBD), which also required 50 ratifications, was adopted in January 2000 and went into force in September 2003, almost three years after its adoption. There are presumably greater incentives to ratify the Nagoya Protocol, especially for the developing countries. For a number of developing countries, however, ratification of an international treaty only marks the beginning of an implementation process, in spite of the fact that any state is under an obligation to comply with a treaty to which it is a Party provided that the treaty has entered into force.[169] If developing countries without proper ABS-legislation apply such approach they are not only going to be in a state of non-compliance in their capacity as provider countries, but they would also have to realize that industrialized countries cannot comply with their user obligations, since national legislation and other implementation measures by provider countries in accordance with the Protocol is a precondition for the obligations of industrialized countries in their capacity as user countries.

For most industrialized countries the approach vis-à-vis becoming parties to an international treaty is normally different. They do not ratify before they are in a position to implement the treaty. Thus, if the first COP-MOP of the Protocol takes place in 2012, there is not much time if the EU and its Member States would wish to participate in the meeting in a capacity of being parties. On the other hand, according to the statement of the Commission this is not relevant, because the EU and the Member States would be in a position to ratify only late 2014.[170] Whether that is true is at least questionable.[171] And in any event, probably some of the above considerations[172] in respect of what the Danish Government should do presently are applicable also to a number of other Member States.

heritage of humankind are already included in the considerants of the Bird Conservation Directive and the Habitat Directive, see *Supra* note 120. Considerant no. 4 of the Bird Conservation Directive refers to migratory birds of the Member States as "a common heritage" and considerant no. 4 of the Habitat Directive to threatened species of wild fauna and flora as forming "parts of the Community's natural heritage". On the concept of common heritage of humankind, see section 7.1 above, and e.g. Jutta Brunnée (2008), "Common Areas, Common Heritage, and Common Concern", in Daniel Bodansky, Jutta Brunnée and Ellen Hey (eds.): *The Oxford Handbook of International Environmental Law*, Oxford University Press 2008, at pp. 561. It might be argued that free access to genetic resources would not necessarily contribute to the conservation of biological diversity and the sustainable use of its components (see section 2 above). Parties, however, would still have to comply with the general obligations of CBD, in particular Article 8 on in-situ conservation, including the requirement of Article 8 (e) to "*[r]egulate or manage biological resources important for the conservation of biological diversity … with a view to ensuring their conservation and sustainable use*."

167. See Article 26 of the Protocol.

168. Cf. Article 27(1) of the Protocol.

169. VCLT Article 26 states that *"[e]very treaty in force is binding upon the parties to it and must be performed by them in good faith*". . Developing countries are, of course, aware of this provision, but in some developing countries ratification of a treaty is, at least from a political point of view, a precondition for achieving the adoption by their parliaments of necessary implementation legislation. This is underscored by the fact that the Protocol is not a self-executing treaty since Parties need to introduce more specific national legislation, regulations or policies to effectively implement the Protocol.

170. *Supra* note 139.

171. See section 7.8 above.

172. *Ibid*.

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