

## BOOK REVIEW

### BIOTECHNOLOGY AND INTERNATIONAL LAW

By Francesco Francioni and Tullio Scovazzi (Editors), Hart Publishing, 2006, 448pp  
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#### **1. Introduction**

The general approach and analytical goals of this book are well summarised in its first two chapters. In chapter one, Francesco Francioni (ab)uses Hamlet's monologue to frame the overall approach of the contributions to the book: the necessary, albeit difficult, balance that must be struck between the dangers that all new technologies pose and the benefits that they could bring to the whole of humanity.

Particularly relevant in the overall context of the book is the question: how should the law cope with this "quest for balance"? As the title suggests, the focus of the book is on public international law. This is not a limitation as such, although such a focus should be kept in mind when assessing the completeness of the book, which arguably gives only scant references to private institutions and mechanisms, such as contract law.

It is worth stressing (as the editors and the authors of each chapter do) that public international law – it regulating relationships between sovereign states – cannot be examined in isolation from the law and the practice of each state actor at the national level. This is particularly relevant when considering the dual – and, as someone not accustomed to *realpolitik* might argue, double-faced – approach that many states have held towards biotechnologies. At the national level, it has not always been so easy to convince local constituencies of the benefits of biotechnologies.

#### **2. The basic questions**

In chapter one, "International law for biotechnology: basic principles", Francioni emphasises four specific questions that in his opinion are particularly relevant for public international law in the field of biotechnology: (i) who owns biogenetic resources (which in turns begs the question which governance models are, or should be, applied to regulate such resources); (ii) what is the relationship between biotechnologies, their regulation and environmental protection; (iii) how should fairness, justice and the equitable sharing of benefits be framed in the context of biotechnologies; and (iv) whether the goals of human rights are conflicting with the current trends in biotechnology development and regulations and, if this is indeed the case, at which point should we try to strike a balance between the two sets of objectives.

Very similar themes are highlighted by Riccardo Pavoni in chapter two, "Biodiversity and biotechnology: Consolidations and strains in the emerging international legal regimes". Here the perspective is focused on the supposed emergence of an "embryonic regime of biodiversity and biotechnology [that] may be extrapolated from [the] vast amount of [state] practice" [pp. 30-31], which has "rapidly accumulated [...]"

over the past few years” [p. 30], although Pavoni is aware that claiming such an emergence might be seen as audacious and premature for four reasons.

First, that although “existing customary law – e.g. the duty to prevent transboundary environmental damage or the principle of permanent sovereignty over natural resources – surely applies to biodiversity and biotechnology”, it is “ostensibly limited and inadequate to address the unprecedented challenges arising in [the] field” and the same can be said of existing international positive law, with specific reference to the General Agreement on Tariffs and Trades [pp. 29-30]. Secondly, the framework resulting from the array of legal instruments put in place since 1992 is extremely fragmented. Thirdly, such fragmentation does not only produce “disconnected legal approaches”, but also “involves considerable tension between legal systems, such as between multilateral environmental agreements [...] and WTO law”, a tension that might “turn into veritable conflicts of norms and thus open up a Pandora’s box of legal issues which are only rarely amenable to solutions in line with the need for unity and coherence of the international legal order” [p. 30]. Fourthly, the speed of scientific and technological advancement of the field begs the question whether the international legal order has any hope of “keeping pace” in any meaningful – and useful – sense of the expression.

The above notwithstanding, Pavoni claims that we are indeed witnesses to an emerging general regime, composed of four “conceptual pillars”: (i) the principle of the *common concern of humanity*; (ii) the principle of *equitable benefit-sharing*; (iii) the *precautionary principle*; and (iv) the principle of *mutual supportiveness of environment and trade regimes*.

This review will proceed along the complementary paths traced by Francioni and Pavoni, highlighting the most relevant linkages to the other contributions in the book.

### **2.1 Who owns biogenetic resources and which governance models are, or should be, applied to regulate such resources?**

Francioni’s first question is answered through a modelling of three possible governance models of biotechnology: the “modern permanent sovereign regime”, the “common heritage regime” and the “common concern” concept.

Francioni, judging from the internal chapter organisation and by his use of the term “concept” rather than “regime”, seems to consider “common concern” a subset of the “common heritage regime”, although it presents sufficient differences from the latter to stand on its own. More specifically, in the “common concern” concept “resources of the world [...] are not ‘owned’ by the international community on the basis of an indivisible title, as is the case of the common heritage; on the contrary, they remain subject to the traditional regime of sovereignty or freedom, but their management requires a holistic approach that takes into account the general interest of humanity in their conservation. In this sense [...] *the common concern serves as a legal basis for legitimising forms of intervention within the sphere of domestic jurisdiction of individual states*, as well as possible limitations on the principle of freedom applicable to common spaces” [pp. 15-16, emphasis added].

Francioni’s view of the “common concern” concept as complementary to the “common heritage” system is opposed by Pavoni, who considers the former as running along “a consensus according to which respect for certain fundamental values is not to be left to the free disposition of states individually or *inter se* but is

recognised and sanctioned by international law as a matter of concern to all states.” Pavoni also considers “common concern” to be one of the main pillars of an international regime for biotechnology emerging from state practice, stressing how “common concern is revealed as the conceptual matrix of a number of agreements aimed at the protection of the essential components of the biosphere and evokes the idea of a global environmental responsibility” [p. 31]. Legally speaking, Pavoni emphasises how “common concern”, besides being a basis for several environmental treaties (such as the Framework Convention on Climate Change, the Madrid Environmental Protocol to the Antarctic Treaty, the Ozone Convention and its Montreal Protocol, the Ramsar Wetlands Convention and the Desertification Convention) is a central element of legal instruments regulating biotechnologies and biodiversity (including the Convention on Biological Diversity and the FAO Treaty on Plant Genetic Resources for Food and Agriculture).

In the end, according to Pavoni, the “common concern” concept/principle consists in the “promotion and enforcement of a rational, prudent and sustainable use of biodiversity and biotechnology” [p. 32]; an approach taken from environmental law which suggests a shift away from a reciprocal approach to states’ obligations in the field. But at the same time, this raises the question: whom should a state have obligations to: *erga omnes* (as would be the common understanding of the United Nations Convention of the Law of the Seas), *erga omnes partes* (a distinction retained in the 2001 International Law Commission Articles on State Responsibility) or only towards another specific state (as would be arguably the case when considering the Cartagena Protocol on Biosafety to the Convention on Biological Diversity)? The question is left open by the author.

The modelling of governance regimes introduced in the first two chapters of the book constitutes the basis for more detailed analysis from the other contributions.

In particular, the “modern permanent sovereign regime”, and more significantly the nuances of its evolution, as expressed in the FAO Treaty on Plant Genetic Resources for Food and Agriculture, is one of the objects of analysis and discussion by Mary Footer in chapter eleven, “Agricultural biotechnology, food technology and human rights”. Notwithstanding the weight that the “modern permanent sovereign regime” continues to have – as testified *inter alia* by the language used in the preamble to the Convention on Biological Diversity (“[s]tates have sovereign rights over their biological resources”) – Francioni is keen to point out how the “modern” version of the regime seems to deemphasise the importance of states’ sovereignty, insofar as “it aims at reconciling the sovereignty of the territorial state with the general interest of the international community in securing conditions to facilitate access to genetic resources for environmentally sound purposes” [pp. 10-11].

The “common heritage regime” is discussed extensively throughout the book, with governance structures and policies for Antarctica being the subject of two different chapters by Patrizia Vigni (chapter six, “Antarctic bioprospecting: is it compatible with the value of Antarctica as a natural reserve?”) and Ann-Isabell Guyomard (chapter seven, “Bioprospecting in Antarctica: A new challenge for the Antarctic Treaty System”). Marine resources, and specifically their bioprospecting, are the subject of two other chapters by Tullio Scovazzi (chapter four, “Bioprospecting on the deep seabed: A legal gap requiring to be filled”) and Giuseppe Cataldi (chapter five, “Biotechnology and marine biogenetic resources: The interplay between UNCLOS and the CBD”).

As is often the case in legal matters, the precise definition of what constitutes bioprospecting is a contentious issue across many dimensions, i.e. understanding what should be the object of such activities in order for them to be considered “bioprospecting”, whether the final goal of such activities – for commercial or for purely research purposes, assuming of course that is indeed possible to mark a precise line between the two – is relevant in categorising them as bioprospecting. Scovazzi highlights these semantic and practical hurdles in the context of the United Nations Convention on the Law of the Sea (UNCLOS), which does not “specifically address either marine genetic resources or ‘bioprospecting’”.

Giuseppe Cataldi’s chapter is particularly interesting insofar as the dialectic relationship it highlights between the Convention on Biological Diversity and the United Nations Convention on the Law of the Seas echoes in the analysis of other legal instruments throughout several other chapters, as a reminder that focusing too much on a single legal instrument does not help a proper assessment of the *statu quo* and is not the best tool when examining potential policies to move forward in a coherent and balanced way. This is true even for the agreement on Trade-Related Aspects of Intellectual Property Rights – that no matter how important “intellectual property rights” are considered nowadays in public discourse, it occupies a refreshingly small space in the economy of the overall book.

Even chapter nine, “Traditional knowledge, biodiversity, benefit-sharing and the patent system: Romantics v. economics” by Hanns Ullrich, although dealing directly with patent law, casts doubts on the capabilities of this particular branch of law to properly address the challenges that modern biotechnologies pose (“[...] to assert that the TRIPs agreement and the Convention on Biological Diversity may be implemented in a ‘mutually supportive’ way is rather misleading in view of the systemic conflicts between the exclusivity-based promotion of innovation, the privileged participation in its profit potential, and the ecologically motivated conservation of biodiversity in open nature [...] The specific causes and needs of safeguarding biodiversity as a matter of protecting the environment, just as the particular causes and needs of pursuing a definite developmental strategy with a view to improving socio-economic standards of living, are only loosely related to the broad reasons underlying patent protection as an incentive system for inventive activity in general”).

## **2.2. What is the relationship between biotechnologies, their regulation and environmental protection?**

With regards to Francioni’s second question, the author’s introductory remarks focus on the potential applications of the principle of due diligence as envisioned by Principle 21 of the Stockholm Declaration on Environment and Development of 16 June 1972 and by Principle 2 of the Rio Declaration on Environment and Development of 14 June 1992. Due diligence establishes an obligation which is “incumbent upon every state to prevent damage to the territory of other states or to common spaces as a consequence of biotechnology activities that entail release of genetically modified material into the environment” [p. 18]. In addition – and arguably even more relevant in the context of biotechnologies, whose cutting-edge nature can make it extremely problematic to assess when “diligence” has been truly carried out – the application of the “precautionary approach” principle is also discussed. The “precautionary approach” principle has been the source of inspiration

for the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, although its precise definition and operative dimension, as Francioni reminds us, is still subject to debate. The principle can either be framed in terms of an obligation for states to “adopt or tolerate the adoption of legislation or administrative measures that are necessary to forestall foreseeable risks for the environment” or according to the more “radical interpretation [...] – still a controversial one – [that] would entail the setting aside or cessation of an economic or technological activity that entailed a serious risk for which no reliable assessment or management method was available”.

What is most interesting about Francioni’s reference to the “precautionary approach” principle is arguably his focus on its procedural dimension, i.e. “the set of procedural obligations arising from the general principle of inter-state cooperation in preventing or minimising environmental risk”. These procedural obligations entail a number of duties, including “the duty to provide information related to the risk posed by genetically modified organisms; the duty to consult whenever differences arise as to the nature and extent of the risk; the duty to allow civil society participation in decisions involving difficult choices between the social advantages offered by technological innovations and the risks posed by such advances; and, most importantly, the duty to provide an environmental impact study of the specific biotechnology upon the environment and health of the people”. Note here the reference to impact studies and to “civil society” participation in biotech-related decision-making [p. 19].

Both issues are highly topical: the second is indirectly one of the subjects of chapter fifteen (Sara Poli, “The EU risk management of genetically modified organisms and the commission’s defence strategy in the biotech dispute: Are they inconsistent?”), and the first, with reference to “traditional knowledge” and communal participation to decision-making processes, is discussed in chapters nine (Ullrich) and thirteen (Maurizio Fraboni and Frederico Lenzerini, “Indigenous peoples’ rights, biogenetic resources and traditional knowledge: The case of the Sateré-Mawé people”); but the issue of impact assessment and the role of science and scientific research are a constant echo throughout several chapters of the book. This should not be surprising, given the nature of the subject matter under examination; but it is worth mentioning how science as a tool for interpretation of positive law is becoming so relevant that, it might be argued, science itself is becoming something akin to a new source of law.<sup>1</sup> The topic is covered extensively – but, for obvious reasons of space, not exhaustively – in chapters eight (Ernst-Ulrich Petersmann, “The WTO dispute over genetically modified organisms: Interface problems of international trade law, environmental law and biotechnology law”) and fifteen (Poli). In particular, chapter fifteen analyses in depth how science is framed in the WTO Agreement on Sanitary and Phytosanitary Measures and how “sufficient scientific evidence” is a condition for restraining measures to be legal under the agreement [pp. 191-192].

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<sup>1</sup> Much in the same way as technology shapes the space of possibilities for actors and, in so doing, dictates what they can or cannot do, thus becoming a kind of law by itself; the point has been raised by numerous social scientists dealing with the nature of technology, but nowadays its formulation in L Lessig, *Code and Other Laws of Cyberspace*, Basic Books, 1999 (“code is law”) is arguably the most famous. The question then becomes how should this principle be reformulated, and how should the law change, when code is not “simply” a tool for expressing information, but the very basic substance of ourselves as living beings?

Pavoni's approach to the "precautionary principle" – which constitutes the "third pillar" of his theorised "emerging regime" – is based on the recognition that "precaution is a cross-cutting principle of the international law relating to biotechnology" [p. 43]. It therefore reaches out from the protection of biodiversity, the area in which the principle was first developed, to biomedicine and human genetics, where the language of some legal instruments (such as the UNESCO Declaration on the Human Genome) seems to suggest a clear role for the principle. However, Pavoni questions whether "precaution" should be understood as a customary or a positive principle of law: while the existence of the Cartagena Protocol on Biosafety suggests we are indeed dealing with positive law, the reality of diverging bio-safety practices and of the lack of a clear consensus in an international forum such as the WTO should be taken into consideration.

### ***2.3 How should fairness, justice and the equitable sharing of benefits be framed in the context of biotechnologies?***

Francioni's third question is perhaps one of the most debated issues in the current international political and legal discourse on and around the life sciences. Francioni's approach is based on a composite recognition that several elements – which are duly examined in other chapters – concur to the definition of any proper regime in this area, including trade policies, intellectual property law, encouraging investment, protecting biodiversity and assisting developing countries. Francioni's most interesting contribution is arguably his suggestion to apply the principle of "common concern" and "common heritage" to benefit-sharing related to the usage of resources in non-sovereign territories, such as Antarctica and the deep seabed; and, for resources found in sovereign territories, rather than "trying to re-conceive new and untested principles of international law", to "place the matter within the scope of application of traditional rules and principles of international law governing the treatment of aliens and foreign investments" and to refer to the two fundamental principles regulating this field of law, namely the "respect for the national sovereignty of the host state of the investment", and "equitable remuneration of the capital invested with the consent of the territorial state" [p.22]. Francioni's remarks are complemented by Pavoni's hypothesis that benefit-sharing, rather than being a "modern variant of the [...] principle of equitable remuneration of foreign investments", is "emerging as a rule of customary law" [p.41]. Pavoni bases his statement on three elements: first, the fact that the "principle at stake has been consistently recognised in various resolutions of the UN General Assembly"[p. 58]; secondly, the existence of "many instances of national legislation and policies endorsing benefit-sharing" [p.41]; thirdly, the "statements and declarations made by state officials within the relevant international fora, such as the TRIPs Council or the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore". Whether this is sufficient to admit benefit-sharing as a rule of customary law is an open question, particularly when considering the wish of some state actors to rely more on the contractual approach that is embodied by the Convention on Biological Diversity rather than on a true multilateral approach.

### **2.4 Do the goals of human rights conflict with the current trends in biotechnology development and regulation?**

Perhaps the single most important answer that Francioni – and, one might argue, the whole book – gives to the fourth question is his statement that “in addressing these questions one cannot overlook the reality that international law, and especially international human rights law, presents conflicting principles and policy goals”. This is a recurring element of all the contributions: biotechnology, as indeed all technologies, put lawmakers in the difficult position to strike a balance between competing goals and constraints. As Francioni notices, above and beyond the antinomy between the principle of states’ sovereignty over resources found in their own territories and the “common heritage”/“common concern” principles, lie even more fundamental confrontations, such as between “the need to preserve freedom of research and the right of everyone to benefit from the advances in science and technology” on the one hand and the “fundamental concept of human dignity and integrity of the human person” [p. 25] on the other.

Throughout the book, several contributions examine the legal instruments and principles that are being devised in order to make sure that biotechnologies are used in an “acceptable and sustainable” manner [p.25]. But beyond the technicalities, it is worth mentioning Francioni’s closing remark that “the development of international law in the field of biotechnology cannot occur independently of a human rights approach”, first because respect for the latter is a fundamental, “constitutional” basis of the international community, and secondly because “international human rights represent the only true universal language for communicating between increasingly extreme and radicalised ethical and religious world views and political conceptions” [p.25]. Although, to be frank, Francioni’s hope that international human rights law might provide a “common ethical ground” seems rather far-fetched, in light of the formal, more than real, adherence to human rights principles that seems to characterise the current geopolitical dynamics, including those that are most relevant for biotechnology law.

### **3. Conclusion**

*Biotechnology and International Law* is an extremely valuable resource that should be held in the highest regard by all researchers interested in how international law regulates the life sciences. While the book is at risk of quickly becoming outdated – given the constantly evolving nature of its subject matter – this is a general problem due more to the tension that invariably exists between the law and almost any subject that it tries to regulate. Moreover, the editors and the authors have taken care to approach the core issues under a general perspective that does not focus so much on the specific details of the subject, but rather on the principles underlying it. This approach, as well as the wealth of bibliographic references to be found throughout the book, makes it a highly valuable contribution for members of the research community interested in this particular topic.

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