PART I

Introduction and systemic issues

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The many faces of modern biotechnology

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A Introduction

The current debate on the implications of modern biotechnology for humans and agriculture epitomises the philosophical dividing lines of modernity. On the one side are fears that modifying DNA endangers life as such. The term 'life' is used in an almost metaphysical way to refer to something unchangeable, perfect, whose integrity has to be preserved at any cost. Any interference with life is strictly taboo and DNA is at the core of it. These views seem to be based on a strict separation between nature and technology. With nature, perfect as it is, one may not interfere or doom is certain – as if our actions can be separated from what nature does, or as if the secret code of our well-being has been enshrined in DNA.

On the other side there is a strongly held belief in the capacity of science and technology to modify biological processes in whatever way would benefit humanity. From this viewpoint scientists do nothing that does not also occur in nature. Any unintended consequences can be controlled by technological means, i.e. there are no unknown or uncontrollable risks either to human health or to the environment – as if our actions could not have any unintended consequences that technology would not be able to deal with.

A compromise between these positions is hardly attainable. While scientists speed ahead finding new facts every day, politicians and regulators battle over fundamental positions on modern biotechnology using scientific information that is twenty or thirty years old based on philosophical concepts of technology from 200 years ago. Today, the development of modern biotechnology is essentially irreversible. A pragmatic scientific perspective on technology cannot ignore this fact.

In some ways, there is nothing new about biotechnology, as the use of 'biological systems, living organisms, or derivatives thereof, to make or

modify products or processes for specific use'[1] has occurred since the earliest human civilisations. For instance, biotechnology helps to produce beer and yoghurt, to conserve food and to treat waste water. In the 1970s, however, 'in vitro nucleic acid techniques' that allow the 'fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers'[2] – techniques referred to as 'modern biotechnology' – opened up a completely new range of possibilities for studying and making use of biological mechanisms. Since then, biotechnology has evolved rapidly, venturing into many new areas and leading to the development of a large number of applications in such diverse industrial fields as medicine, food production and computer technology. Modern biotechnology has become a key technology in our time.

The different applications require specific policy considerations. The effects on human health vary not only according to the specific uses of the technology but also according to the hazards presented by the applications. A food product that is ingested on a daily basis requires completely different policy considerations to a bio-fuel. Again, a food-protein cannot be treated in the same way as a pharmaceutical. There is also a great difference between the regulation of biotechnology at the research stage and its regulation when marketed. Similar considerations are valid for the ethical or environmental implications of modern biotechnology. There are no unique characteristics that can be used as guidelines when regulating biotechnological applications. Rather, each field of application has to be looked at separately.

This book attempts a pragmatic approach to looking at the many faces of biotechnology. Its focus is the challenges that arise from biotechnology for international trade regulation. At its core lies the central question of whether trade law is sufficiently well equipped to deal with modern biotechnology or whether there is a need for new instruments, e.g. a WTO agreement on biotechnology as suggested by Cottier (see Cottier, chapter 2, below). The contributions were initially prepared for the World Trade Forum 2005, held at the World Trade Institute in Berne, Switzerland, and subsequently revised. They provide a stimulating and thought-provoking overview of the subject matter.

[1] Art. 2 of the Convention on Biological Diversity (CBD).
[2] Art. 3(i) of the Cartagena Protocol on Biosafety to CBD (Cartagena Protocol).

B Sustainable development, modern biotechnology and international trade: conflict and coordination

Any policy framework today has to contribute to sustainable development, that is, development 'that meets the needs of the present without compromising the ability of future generations to meet their own needs', according to the Brundtland Report.[3] Although there are very few hard criteria that flow from the concept, it should still influence our current thinking as a guiding principle. Its three elements – economic, social and environmental sustainability – offer a valuable normative framework for thinking about the many conflicting views on biotechnology and international trade. The following paragraphs use this framework to synthesise the – sometimes concurring and sometimes conflicting – contributions to this collection and to point to issues that were not raised by the authors.

1 Environmental sustainability of modern biotechnology

The metaphysical critique of modern biotechnology is most prominent when it comes to the environmental effects of genetically modified (GM) plants and microorganisms. There are fears that modified plants may pass on their modified DNA to soil microorganisms that will develop into killer bacteria. Others fear that GM plants are uncontrollable and will displace entire populations of wild plants, thereby drastically reducing biodiversity or destroying entire biospheres. Or, biotech plants might kill large groups of animals due to proteins ingested from GM plants. These fears are frequently combined with opposition to economic globalisation, to the concentration of (seed) industries or to intensive farming. The proponents of modern biotechnology, on the other hand, deny that any of the risks posed by GM organisms are new or real.

As always, the truth probably lies somewhere in between. Assessing the environmental sustainability of biotechnology requires a case-by-case approach that takes into account the specificity of an application as well as the specific environment in which it will be used. It makes a difference whether a product will be introduced into the environment directly or could end up in the environment only by accident, and

[3] Report of the World Commission on Environment and Development, 'Our Common Future' (Brundtland Report), UN Doc. A/42/427 (1987).

whether it will be used on a large scale or only for test purposes. The potential advantages of the specific product, such as lower pesticide use, increased resistance to environmental stress, etc., have to be considered as well. Generally, the debate tends to ignore the advantageous effects that GM products may have on the environment, e.g. where bio-remediation could be used to clean up waste, where they lead to cleaner industrial processes or when bio-fuels could lead to reduced emissions of greenhouse gases.

In light of this, each WTO Member has to find its own policy mix to ensure environmental sustainability in its territory. The trading system should not interfere but should prevent domestic policies being adopted for illegitimate reasons. There has often been criticism that the science-centric approach of the WTO's Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) adopted for this purpose fails to properly address the specific concerns with modern biotechnology. However, when a WTO Member claims the existence of environmental risks when adopting a trade-restrictive measure, who other than scientists can provide a basis for the existence of these risks? Not even the Cartagena Protocol crosses that threshold (see Perrez, chapter 11, below on the compatibility of the Cartagena Protocol and the SPS Agreement). If domestic governments adopt measures that restrict trade in biotech products for ethical reasons or because consumers simply do not want biotech food, then they should not criticise the SPS Agreement's scientific basis. Consumer protection or *ordre public* measures are not environmental measures and should not be framed in terms of environmental regulations.

Much of the dispute between the USA and the EC arises from the different perceptions of modern biotechnology and the resulting regulatory approaches. In the EC, modern biotechnology is generally viewed with suspicion. The EC has therefore enacted specific regulatory tools for the approval and monitoring of all GM products. In the USA, the focus is more on products and their potential differences from conventional products and less on the technology. Only if such differences exist and have a negative impact on consumers or the environment may such products not be marketed. Producers have to ensure the safety of their products and liability is the consequence it they fail to do so. Whether the European approach is consistent with WTO law is contentious. The legal problems with the EC measures stem not from their different approach as such but rather from the inconsistent application of that approach. Although there has been a general policy decision to allow

GMOs on the EC market, the actual regulations and their application almost entirely prevent the use of GMOs within the EC. It is no wonder that the EC faces a difficult challenge in defending its regime before the WTO. Questioning the appropriateness of WTO law misrepresents the problem.

So far, no farmers in the EC have used GMOs. The discussions of the past few years have now started to focus on whether the existing regulatory environment is adequate for agricultural production with GMOs. Some question whether GMOs should be planted at all in Europe in light of the prevalence of small farms and the greater mixture of conventional and organic farming. Others caution that there is a need for specific regulatory safeguards such as rules on coexistence and, in particular, liability (see Petitpierre-Sauvain, chapter 8, p. . . ., below). Some countries such as Switzerland have already adopted specific liability regimes. The debate is also taking place within international environmental law. Under the Cartagena Protocol, negotiations on international obligations to enact liability rules for living modified organisms are currently being conducted, as mandated by its Article 27. Whatever the outcome of the negotiations within the framework of the Cartagena Protocol, there should be no concerns that WTO law would not support it. No conflict between liability rules negotiated under the Cartagena Protocol and WTO law is evident. As Perrez emphasises (see chapter 11, below) there is no *a priori* conflict between the two legal regimes and there are ample legal tools that can be applied to support their mutual supportiveness. Boisson de Chazournes and Mbengue (see chapter 10, below) agree and call for strengthening the principle of mutual supportiveness between the two systems of law.

Some authors call for strengthening the environmental sustainability of modern biotechnology by taking environmental risks into account in patent procedures. Expecting patent officers to assess environmental implications might not be the best solution however, unless a patent claim relates to an invention that, if implemented, could obviously have disastrous effects on the environment (and hence violate *ordre public*). Patent officers do not have the expertise to assess environmental risks. Considering environmental risks at the patenting stage would require risk assessments by qualified personnel. This would increase costs both for the administration as well as the patent applicants. Moreover, at the patenting stage, researchers usually have very little concept of the potential environmental or health risks of any product that is

ultimately developed from the patented invention. Pharmaceuticals, for example, take up to ten years to progress from patenting to the marketing stage. Such a requirement would also disadvantage smaller and medium-sized companies and research institutions, as bigger companies can more easily spread development costs and financial risks over other products and profit from greater economies of scale. It would be inappropriate to perform risk assessments on all patent claims preventively.

Finally, governance aspects require giving thought to the capacity of developing countries to administer complicated regulatory safety regimes. Smaller developing countries, in particular, face problems in this respect, for example when trying to reconcile biosafety with food security due to a lack of expertise and effective governmental control. Indeed, research in modern biotechnology and the handling of GM plants and animals require a sophisticated governmental system including regulations that can guarantee that newly developed products are scrutinised and that existing applications are implemented safely. From this perspective, it is important to ensure that developing countries are ready to meet these governance challenges. The food aid controversy highlights these difficulties. A developing country allowing food aid into its territory in the form of GM-seeds (mainly GM corn) faces the challenge of ensuring that these seeds are only used as food. Should farmers plant the seeds – as is the custom in many developing countries – a country that has no control schemes in place will not be able to remove the seeds from its production cycle. This would effectively turn the country into a country producing GMOs because of the low tolerance thresholds of food-importing countries. Needless to say, neither can the environmental effects be controlled. Once milled, the corn no longer poses the same risks – corn flour cannot be planted. That was one of the main reasons why countries such as Zambia insisted on not accepting whole grains of GM corn as food aid. It is important that developing countries are supported and can obtain the technical assistance necessary to deal with these problems. Providing a regulatory framework for biotechnology in the Cartagena Protocol could help too. Any such framework would have to take into account the criteria that stem from WTO law.

In trade law, the question remains how and whether developing country aspects can be taken into account. It is unclear how the need for special and differential treatment can be factored into the WTO Agreements. Obviously, no developed country will lower its

environmental or health standards for products from developing countries. Specific support schemes for developing countries and help with installing quality management systems will probably remain the only realistic options. Developing countries' own regulatory systems do not, however, have to be scrutinised according to the same rules as the environmental regulations of developed countries. Developing countries could be allowed, for example, to restrict trade in biotech products by referring to governance problems.

2 *Economic sustainability of modern biotechnology*

Technological process depends to a large extent on private innovation. Private innovation can only take place in an environment that provides appropriate incentives and the degree of freedom necessary to venture into unknown territory. Intellectual property rights, especially patents, are the traditional legal instruments that guarantee exclusivity on various forms of innovations and thereby allow the inventor to profit from his ideas. Indeed, biotechnological inventions can be patented like other inventions provided they fulfil the general criteria of patentability laid down in the TRIPS Agreement. However, these criteria are not applied equally in all jurisdictions throughout the world. Many States today allow for the patenting of organisms, plants and animals developed with the help of modern biotechnology. In other countries, protection is unavailable or is granted only by means of plant variety rights, also called *sui generis* rights. Most developed countries allow patenting of biotechnological inventions. In these countries, the debate centres on the question of whether DNA sequences isolated from an organism should be patentable as well. Many developing countries tend not to welcome patents on organisms or on DNA sequences.

Intellectual property rights have become a genuine field of trade regulation since the Uruguay Round. Indeed, the question as to whether TRIPS should mandate WTO Members to allow patents on biotechnological inventions has taken centre-stage in current negotiations. Yet, in light of the diverging positions, it is not surprising that the debate on appropriate protection of biotechnological inventions in the WTO is still ongoing. So far, no agreement has been reached on the revision of Article 27.3 of TRIPS that allows WTO Members to exclude plants and animals from patentability (see van Overwalle, chapter 4, below).

Beneath this debate a bigger controversy is lurking. What is at stake is the delicate balance underlying intellectual property systems between

the granting of a private monopoly for using a certain piece of information and technological progress at large. Ultimately, such limited exclusive rights should contribute to overall welfare and not lead to a disproportionate concentration of market power. Views on how the appropriate balance should be struck again vary from country to country. India, for instance, is at the forefront of those WTO Members that are concerned about patents on biotechnological inventions because they fear traditional livelihoods being put at risk. Other countries such as the USA build their industrial policy on private property and, hence, are very much in favour of biotech patents. Very little is known about the correlation between modern biotechnology, patents and welfare. More studies are urgently needed on the effects of the contemporary practice of patenting biotech inventions on competition including such phenomena as strategic patenting and patent clusters. Can the need for large economies of scale in today's global economy be combined with an adequate scope of concentration of patents in the hands of big companies?

Related to these issues is the question of who should benefit from patents. Many agree that countries that are rich in genetic resources, mostly developing countries, should benefit from the use of such resources by industry that resides mostly in developed countries. The way in which industry can gain access to genetic resources and the sharing of the benefits that stem from these resources constitute some of the most important issues of distributive justice today. It is to be hoped that, ultimately, extending territorial sovereignty over genetic resources will also contribute to their preservation. Similarly, if knowledge that contributes to a patented invention is held by traditional communities, these communities should benefit from its exploitation (see Lenzerini, chapter 6, below).

When there are discussions on what might be the appropriate forum for international rules in this area, the WTO should play an important role. Together with many other areas such as health and environmental regulation, the protection of intellectual property rights is a genuine trade issue today. The amendment of Article 27.3 of TRIPS should not be separated from the protection of traditional knowledge and access to genetic resources.

Innovation does not depend only on intellectual property. Industries are influenced by the entire regulatory environment that relates to their activities. Excessively burdensome regulations – for example, the requirement for conducting risk assessments at the patenting

stage – can have the effect of restricting activities too much. Burdensome regulation also tends to favour larger economic actors, a factor which developing countries in particular might want to consider if they wish to foster domestic research capacity and smaller start-up companies. A regulatory environment that provides inadequate guidelines, though, could lead to market inefficiencies and be detrimental to national welfare. The challenge is to find the appropriate balance between these poles. Again, this cannot be done without looking at the strategic considerations, i.e. a general vision of what role biotechnology should have in a given society.

The appropriate role for the WTO framework cannot be to determine its Members' biotechnology policy. Its main task must be to avoid national policies being allowed to result in protectionism, i.e. illegitimately restricting international trade. It is for the WTO Members to find the appropriate balance, taking into account other international legal obligations, especially in multilateral environmental agreements (MEAs) such as the Cartagena Protocol. In academic discussions and political discourse, this relationship is often seen as precarious, thus making it difficult for WTO Members to reconcile their international legal obligations when determining their own biotechnology policy. Often, the focus is on the danger of the environmental regime being trumped by trade rules. Yet, economic opportunities may also be impaired by environmental rules. It is important to consider that, in the trading regime, some fundamental principles are enshrined that should not fall by the wayside. In this sense, the Cartagena Protocol should also be interpreted in accordance with WTO law and not only *vice versa*. In any case, in legal practice, the controversy is less intense. The Cartagena Protocol and WTO Agreements do not conflict *per se* (see Perrez, chapter 11, below). Indeed, the onus should be on the mutual supportiveness (see Boisson de Chazournes and Mbengue, chapter 10, below) of the two regimes and thus on strengthening their coherence.

3 Social sustainability of modern biotechnology

The advent of a new technology carries the potential for income redistribution. Especially within the NGO community, but also within developing country governments, there are concerns that allowing modern biotechnology products to be used in agriculture could work to the detriment of subsistence farming, rural livelihoods, indigenous