Regulating Modern Biotechnology in a Global Risk Society

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Regulating Modern Biotechnology in a Global Risk Society

Challenges for Science, Law and Society

Inaugural Lecture

delivered on the occasion of the appointment to
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by

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Compared to almost any other object that starts with the letter D, DNA is very safe indeed. Far better worry about daggers, dynamite, dogs, dieldrin, or drunken drivers than to draw up Rube Goldberg schemes on how our laboratory-made DNA will lead to the extinction of the human race.

(James Watson, Nobel Laureate for his pioneering work on DNA)

Vice-Chancellor,
Ladies and Gentlemen,

It has been observed that there are three historical events of equal importance.[1] Event one is the creation of the Universe, which all of us will agree was a significant event. Event two is the appearance of life. Life is the kind of phenomenon one might occasionally feel disenchanted about but, in general, we all accept its wider significance. And event three is the event of modern biotechnology. Modern biotechnology is of such significance because it allows humans to gain ultimate control over our universe and even human life itself.

It is puzzling that 'law' should not feature in my top-three most important events. This is a curious and counter-intuitive confession for any lawyer to make, and indeed, it has been a close call. Because, when it comes to control, law stakes a monopolistic claim. And to protect that monopoly, the law has constantly crossed swords with those who followed the laws of the universe, life, or science. The law often initially emerged victorious, but ultimately has had to concede defeat in the face of the superior powers of life and science.[2]

The history of science and technology is littered with examples of scientists who were forced to accept the supremacy of law and policy, over the laws of science and nature. Galileo offers a rather sad example of such unfortunate fate.[3] But this did not stop Galileo from setting in motion a process of what has been called 'decentering': a painful rejection of our instinctively self-centred view of the world, and our unique place in the universe.[4]

Biotechnology again is forcing humans to abandon feelings of uniqueness, but this time as a result of discoveries at micro-level. On the basis of earlier ideas, we used to believe that we are made of a matter completely different from, say, cauliflowers, or other plants or animals. We now realize that we share DNA, the basic mechanism for encoding and transmitting genetic information, with hamsters, spi-

ders, tulips and cockroaches. Science has embraced this discovery, and the possibilities it opens, but our psyches may never get accustomed to the idea that we do not possess a unique 'self'.[5] It is not clear what psychological harm this discovery will eventually turn out to inflict, or whether it is a harm the law ought to protect us against.[6]

Having finally arrived at the issue of modern biotechnology, two centuries after Galileo faced what he undoubtedly felt were irrational laws, its founding fathers fared little better. Gregor Mendel, a monk by vocation, laid the foundations for modern biotechnology in the Monastery of Brno in the mid-1850s. Unwisely, he chose to do this in ways that failed to impress the archbishop of Prague and Pope Sixtus IV, who therefore threatened to close the Monastery, including Mendel's state-of-the-art research lab.[7]

The regulatory instrument of God's choice, in all these early instances, was (and presumably still is) what present-day regulatory theory would term, 'command-and-control regulation'. Moses came down the mountain clutching Ten Commandments, and they were literally written in stone. To be sure, other more flexible regulatory instruments would have been feasible. For example, God could have opted for voluntary codes of conduct, guidelines, principles, a system of tax incentives, or even market instruments. Yet, He insisted on a rigid, top-down system of ten highly prescriptive rules, backed up by a particularly dissuasive set of sanctions. Neither did he seem worried about the democratic legitimacy of his commandments, about which His people were never consulted.

One can only feel sorry for Galileo and Mendel, who were unfortunate enough to practice their science at a time when regulatory theory was still very much in its infancy, and so profoundly dominated by the clergy.

In this lecture, I will show that, at the present stage of our understanding of genetic science, the law has key contributions to make to ensure that biotechnology will turn out to be a blessing, rather than a curse. It must first facilitate and supervise public engagement in finding solutions to the challenges that lie ahead in the fields of risk, ethics and governance. It must then translate the product of this process into a regulatory regime that is both effective and efficient. This regime might come to rely on command-and-control regulation, voluntarism or a combination of these and other instruments.

REGULATING MODERN BIOTECHNOLOGY

In the past, I have spent much time thinking about the control of hazardous technologies. It is my experience that lawyers tend to be oblivious of technology, but nonetheless are only too happy to regulate it. In this sense, in the four centuries that have passed since Galileo's inquisition, science has evolved a whole lot more than the lawyers whose job it is to harness it.

For todays' question, therefore, we first of all must articulate the hard core of challenges this technology poses to its legal control. We will see that a degree of 'genetic exceptionalism' is justified, because genetics indeed gives rise to a number of new challenges for law, science and society.[8] If we are able to identify these novel features, this might provide vital clues about the requirements of the *novel law* we need. Since novelty and inventiveness are concepts mostly alien to the legal mind, possibly with the exception of a handful of patent lawyers, this is a particularly tough challenge.[9]

So, what is biotechnology? A UN definition refers to 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'.[10]

As I speak, in laboratories, research departments and hospitals around the globe, thousands of anonymous, but highly motivated scientists are quietly working to advance this technology, and it is changing our world. Moreover, it is doing this at a pace faster, and in ways more fundamental than anything witnessed before. This technology has the potential to create new life, including humans, to eliminate faults or to make them perform services, such as the supply of human donor organs. It is a technology that appears to allow us to become masters of our own evolution.[11]

There is much to be said for biotechnology. With the depletion of fossil fuel reserves, expected to run out within three to four decades, the engine of our industrial age is about to grind to a halt. The price for our material well-being comes in the form of catastrophic climate change, irreversible pollution of oceans, soil and air, over-population and starvation in much of the world,[12] and biodiversity loss at a rate of three species between now and the time I have finished this lecture.[13]

In short, the human race is in desperate need for a break that will change its fortunes. Biotechnology may be our last hope. Its claim is that it can feed the hungry, heal the sick, and supply alternative and clean forms of energy.

But despite its staggering potential, biotechnology harbours risks. Genetically Modified Organisms (GMOs) released into the environment have the potential to destabilize the biosphere. Newly made viruses may provide lethal and cheap weapons for terrorists.[14] Advances in human genetics increasingly force parents to decide, partly on the basis of their spending power, the futures of their children well before they are even born. Genetic information allows us to look into our future health, but this information may also become available to employers, insurers and government agencies and applied for their own purposes. Genetic screening policies could give rise to the emergence of a 'genetocracy', organising itself in informal biological caste systems.

Biotechnology is therefore bringing fundamental, all-encompassing and irrevocable change to our world, and this has not left the law unaffected. Patent lawyers need to explain the difference between 'discovering' DNA and 'inventing' it,[15] environmental lawyers must understand what we mean by 'nature' or 'natural',[16] medical lawyers must come to terms with basic concepts such as 'life' and 'disease', and family lawyers have trouble explaining what we mean by 'parent', and even 'family'.[17] What all these examples have in common, is that the very building blocks of hitherto mature systems of law are shaking at their foundations. All these basic legal concepts, so vital to the law and ultimately the stability of our society, are now in turmoil.

It is obvious that the State should bear primary responsibility for the scale, direction and effects of biotechnology. However, for this to be possible, these monumental changes of the recent past have yet to be matched by changes to our political and legal structures.[18]

Ultimately, the aim of my research group is to make contributions to suggesting such necessary reforms. There are reasons to be optimistic: as the Centre for *Environmental* Law, we are well-placed to make valuable contributions to the design of a regime that stimulates the potential of biotechnology and at the same time controls its risks.

For this, we first need to understand what complications we can expect in pursuit of this aim, and I believe there are four broad themes that define the emerging discipline of 'biotechnology law'.

First, in common with the environmental debate, in all cases there remains uncertainty about the environmental, ethical, social and economic externalities,

or 'risks' of this technology. Apart from scientific uncertainty, an additional dimension of biotechnology is that the regulation of risk is further complicated by different but equally valid lay and expert perceptions of risk. Current policies to educate the 'lay' public alone, will not resolve these differences in perception and, without some other mechanism, the associated regulatory paralysis is likely to remain.[19]

Second, in marked contrast to environmental law, where the importance of ethics has (unjustifiably) been underplayed,[20] ethics are at the forefront of the regulatory debate in biotechnology. Ethical principles of course dominate the regulation of human genetics, but they also shape debates in the field of patents and agricultural biotechnology. Clearly, the accommodation of ethical principles in any regulatory regime poses new challenges, in particular in terms of governance.

Third, and in common with environmental regulation, national and trans-national governments are beginning to embrace the idea that the regulation of biotechnology, given its potential impact on almost all aspects of human existence, must be reflected in inclusive forms of genetic governance. Governance refers to a process that broadens and changes the meaning of government. It implies collective action from multiple, mutually influencing actors, both within government and beyond its formal authority. Inclusive forms of governance may be the ideal, but the reality is that globalization[21] of firms, markets, and regulation, severely restrict the roles of states and its citizens, and even of powerful organizations such as the European Union (EU).

Finally, because the regulation of biotechnology is still in its infancy, little experience exists with the development of suitable regulatory instruments, let alone with their implementation and enforcement. In the course of this lecture, I will draw upon the considerable knowledge that environmental regulatory theory has produced in this respect.

However, the single most important legal instrument that shapes the development of biotechnology is property. The most important source of property rights in this field is constituted by patents. Patent offices and tribunals are obviously not 'regulators' in the classical sense of the word, but the power that these bodies enjoy to interpret patent law, including the ethical acceptability of patent applications, amounts to regulation in fact. For these reasons, I will pay separate attention to biotech patents.

In summary, the regulation of biotechnology revolves around four broad themes. (1) Regulators must deal with scientific uncertainty (risk) and; (2) they must formulate and apply (ethical) principles for the protection of present and future generations; (3) they must offer special guarantees that secure the legitimacy of genetic governance through public participation and transparency in a globalized world, and (4) they must employ a variety of different instruments for the regulation of extremely diverse applications of biotechnology, all of which function in the shadow of biotech patents.

In respect of these four themes, there exists considerable common ground with environmental regulation, so that we can hope to set in motion a process of cross-fertilisation.[22] At the same time, biotechnology represents a discrete regulatory field, at times calling for 'genetic exceptionalism', i.e. a unique approach that in many respects should differ from environmental regulation.

I shall now develop these four themes in turn with a particular focus on two applications of biotechnology: agricultural biotechnology and human genetics.

Risk and Future Generations

Turning to the issue of risk first: 'risk' is a function of two variables – the likelihood of any particular impact, and its scale.[23]

The regulation of risks posed by biotechnology is difficult for two reasons. First, biotechnology gives rise to more than just *one* type of impact, as is the case with Genetically Modified (GM) crops. The multitude of impacts (such as health, ecological, and social) leads to the problem of 'incommensurability', i.e. that no single criterion, such as mortality, can be used to quantify these different potential impacts. We therefore cannot avoid subjective choices about the kind of impact we find most important. For this reason alone, references to 'sound science' and 'science-based' risk regulation are inherently flawed, and public participation in risk regulation a necessity.

Second, dealing with the likelihood of those impacts is fraught with problems. This is because cutting-edge biotechnology exists in the twilight world of scientific 'uncertainty'[24], and even 'ignorance'.[25] We simply do not know enough to rely on classical probabilistic risk assessment and risk management techniques.[26]

It is in this context that the 'precautionary principle' is important. Originating in environmental law, it currently features in many national, regional[27] and global[28] legal texts. It instructs that, where there are threats of serious irreversible damage, lack of full scientific certainty is no reason for postponing measures to prevent the risk from materialising.

The precautionary principle is evolving into a core principle, not just of EU environmental law,[29] but is beginning to find its way into medical law,[30] and has already become firmly established in food safety law.[31] In other words, the law concerning risks associated with human genetics and GM food are converging around the precautionary principle.

However, in so far as risks are borne exclusively by *present* generations of patients or consumers who, unlike the environment, *are* in a position to speak up for themselves, I find the analogy with the environment tenuous.[32] Cynical as this may sound, in the larger picture, injury or even death of a patient or consumer is not 'irreversible' in the sense of the precautionary principle. Application of the precautionary principle for this kind of risk may stifle innovation in medicine and agriculture. I would therefore argue for caution in adopting the precautionary principle in fields other than that from which it originated.

By the same token, however, the precautionary principle, *could* provide added guidance for deciding about genetic interventions that affect future generations, in the same irreversible way as environmental degradation affects future generations. I am thinking of reproductive cloning, permanent changes to the human genome, and xenotransplantation.[33] In the light of the precautionary principle, such irreversible practices become problematic in so far as they harbour risks to future generations.

Governance and Globalization

I now turn to the second theme of biotechnology law: governance. If I have to identify a single most important factor that is pushing questions of 'genetic governance' to the forefront of debates about the regulation of agricultural biotechnology, it must be concerns about the *democratic legitimacy* of those rules. These concerns are premised on the idea that scientific expertise, like other forms of democratically delegated power, is entitled to respect only when it conforms to

norms of transparency and deliberative adequacy.[34] Democratic legitimacy, and associated values of transparency and accountability, is under threat by both the globalization of biotechnology regulation, as well as by exclusive, expert-driven models of the regulation of science and technology.

These two threats to the democratic legitimacy of biotechnology regulation converged in Seattle and led to a violent revolt against the World Trade Organization (WTO). The WTO claims powers to review national or regional laws, including patent laws, against its trade rules.

The legitimacy crisis created by the WTO stems from a number of facts. Its policies are determined by its member states, without any other forms of direct democratic input and law-making occurs in the context of dispute resolution, which by definition is unaccountable.[35] Historically, WTO policy also has been driven by special interests, in particular those of multinational corporations, and industrialized powers such as the US, EU and Japan.

The contrast between WTO law and the UN Biosafety Protocol is striking.[36] Both regulate trade in GMOs, but a comparison between the way in which those two sets of rules came into being, suggests that the WTO can learn important lessons from global environmental governance.

The 1992 UN Earth Summit in Rio de Janeiro brought together a Global Forum of NGOs, drawing representatives from 7000 organizations, spectacularly outnumbering the 150 governments present. The Rio process was a constitutional moment, connecting citizens to global environmental law-making.[37] By comparison, WTO law-making through its dispute settlement procedures, has an obvious democratic deficit.

A similar contrast between relevant WTO law and the Biosafety Protocol emerges, if we focus on the legal instruments they employ to regulate movements of GMOs. The Protocol revolves around an Advance Informed Agreement procedure,[38] which is a manifestation of 'information based regulation'.[39] A Biosafety Clearing House further instils transparency for third-countries and citizens alike. The Protocol also carries a labelling requirement for GMOs intended as food products.

Under WTO law, such measures restricting trade in GMOs are subject to a simple 'prohibition unless derogation' framework, and the legality of national labelling requirements relating to GMOs is dubious at best. Neither is there any

equivalent to the Biosafety Clearing House mechanism to provide transparency in a state's decisions to authorize imports of GMOs.

The EU also claims significant powers in the field of agricultural biotechnology.[40] What can we say about the legitimacy of those rules? In order to answer this question, it will suffice briefly to focus attention on Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Directive 90/220/EEC (Deliberate Release Directive).[41] The Directive contains a Community authorization procedure for the release of GMOs into the environment. Community authorization means that, once a product containing a GMO is authorized in, for example, Lithuania, other countries may no longer restrict the placing on the market of that product.

In our example, Community authorization follows on the basis of a risk assessment carried out by Lithuanian authorities. This system of 'multi-level governance' produces an obvious legitimacy deficit.[42] After all, one single national risk assessment now determines the implications of a GMO for all other EU Member States. In such cases, Member States may exercise a degree of control only by:

a) raising objections;
b) having recourse to a so-called safeguard clause.[43]

However, in both cases, decisions are transferred back to Community level by virtue of a so-called 'commitology procedure'[44] referred to in Article 30(2).[45] Decisions taken by the Regulatory Committee pursuant to Article 30(2) are Community decisions.[46] The effect of this procedure is to exclude the directly elected European Parliament, which in such cases may merely 'inform the Council of its position'. Equally serious, for reasons of legal procedure, individual legal action against manifestly erroneous decisions of this Regulatory Committee will rarely be available.[47]

On the positive side, public consultation is a core principle of the Directive.[48] The Deliberate Release Directive also establishes a labelling scheme, informing consumers of GMOs in food.[49]

The impact of globalization on the legitimacy of biotechnology law might be presumed to be a less dominant dynamic for human genetics than is the case for agricultural biotechnology. Indeed, in matters concerning ethics, states traditionally enjoy much greater autonomy than in the area of trade. The EU, for example,

does not claim competence to harmonize ethics. But the EU *is* actively promoting research in the field of human genetics, and has proposed ethical guidelines for EU-funded embryonic stem-cell research.[50] Obviously, these guidelines will influence national regulatory choices, and may amount to *de facto* regulation.

The fact that medical services are big business again triggers processes of globalization. Globalization of markets (in pharmaceuticals and medical treatment) stimulates mobility of patients, doctors and researchers. As the example of abortion tourism to Holland and Spain shows, the effectiveness of national laws restricting access to medical services on ethical grounds is limited.[51] Also, EU legislation requiring mutual recognition of medical and other academic diplomas encourages brain drain to permissive jurisdictions, in particular the United Kingdom, where stem-cell research is stimulated.[52]

Apart from globalization, the legitimacy deficit of the regulation of human genetics is exacerbated by two additional dimensions.

The first is directly related to the prevalence of the ethical paradigm. In the sphere of human genetics, ethical pluralism rules, with positions ranging from an uncompromising emphasis on 'human dignity', to utilitarianism and 'free choice' neo-liberalism. This means that a large proportion of citizens, in particular those emphasizing the value of 'human dignity', will *always* question the legitimacy of any compromise position. No amount of procedural fair play appears sufficient to compensate for this legitimacy problem.

The second stems from the fact that the science of human genetics constitutes a regulatory target that moves frighteningly fast. Under such circumstances, the law can either accept being perpetually overtaken by scientific progress and become obstructive, or it can employ open-textured drafting that over time is given contemporary significance and meaning by courts and other adjudicators. Whereas the latter offers a practical solution to a real problem, courts are not regulators, and such solutions compound the legitimacy deficit that troubles the regulation of human genetics.[53]

There can be little doubt that the EU is taking all these concerns seriously.[54] Advice of the scientific committees is available on the internet, public consultation of the public is made compulsory by the Deliberate Release Directive, and an independent Group on Bioethics was established by the Commission, whose opinions are published. More generally, the EU has made real progress with the

adoption of provisions on transparency, access to documents and access to justice. Crucially, the precautionary principle underpins EU biotech regulation. This allows for a wide range of values to play a role in risk assessment, and fosters transparency. It gives a voice to minority opinion, and allows early involvement of civil society.

This process of democratising EU regulation of biotechnology is complicated by the fact that it involves different levels of governance, where different cultures dominate. However, such challenges are not entirely new. Nature 2000, which is an EU network of specially protected habitats, offers an interesting model of relatively successful multi-level governance of a common good. Such experiences provide useful guidance for future improvements to EU genetic governance. The task ahead is a daunting one. The democratisation of expertise entails some difficult trade-offs between the values of legitimacy and efficiency, and those of simplification and participation.[55]

Ethics

Next to 'risk' and 'governance', the third broad theme of biotechnology law is constituted by ethics. The regulation of human genetics in large measure revolves around resolution of ethical questions. However, important ethical questions *also* arise in the context of agricultural biotechnology and biotech patents. One may ask what the lack of consensus about these ethical conflicts tells us about the maturity of this branch of law. A mature body of law might be expected, substantively, to provide answers to questions concerning the use of genetics, set boundaries, contain mechanisms for its enforcement and, procedurally, ensure its legitimacy. For as long as basic ethical dilemmas remain unresolved, however, regulators will be looking for ways of meeting a role that has yet to be actually defined.[56] To some extent, therefore, asking how the law should regulate genetics amounts to asking it to run before it can walk.

And yet, at present, practical ethical questions arise not so much in the context of spectacular futuristic techniques, such as reproductive human cloning, or improving the human genome (germ-line intervention), but much more practically in the day-to-day clinical practice of genetic testing. The social and legal implications of genetic testing are profound. It allows for an increasingly detailed look

into our future health and that of others, including that of the unborn. Genetic information is of immeasurable commercial value for pharmaceutical industries, insurance companies and employers. Of equal concern is the interest states have in this information, for example for purposes of social policy and the prevention of crime.

It is not possible to elaborate on the countless ethical dilemmas of privacy, confidentiality, autonomy and informed consent to which human genetics gives rise. However, it is clear that the law must provide answers to these and many other future dilemmas. Most of these ethical questions are not 'new', and hence may be resolved by building upon existing experience. At the same time, we need to be careful not too easily to switch on the 'business as usual' mode.

The scale with which genetic tests for thousands of illnesses can be applied, and the precision of outcomes *does* lead to novel problems. For these new issues, I feel that medical law should branch out to disciplines traditionally alien to it, in particular environmental law.

The precautionary principle has already been alluded to in the context of risk regulation. A second and important example that addresses ethical concerns is informed consent. Informed consent requires consent by a patient to a surgical or medical procedure, or participation in a clinical study after having been informed of the risks involved.[57] The instrument of informed consent has subsequently been adopted by the environmental movement, and now plays a central role in legal regimes that regulate trans-frontier movements of hazardous wastes and, as has been seen, GMOs. It is also undergoing a remarkable development in the field of patent law. The instrument of informed consent has thereby developed from a bi-lateral legal instrument in the sphere of medicine, to a multi-lateral, community instrument, in the sphere of the environment and patents.

The accelerated emergence of human biobanks[58] in my view necessitates a similar development within medicine. The very nature of these biobanks, allowing the mass storage of genetic information over indeterminate periods of time, makes continued adherence to bi-lateral informed consent problematic for both practical and theoretical reasons. Practically, to obtain individual consents from such a large number of people is prohibitively expensive and difficult. Theoretically, if the Human Genome is regarded as 'the common heritage of mankind', there is much to be said for moving away from the traditional bi-lateral consent, towards a single, generic 'community consent'. A presumption in favour of individual consent

could then be rooted in considerations of solidarity and the public interest.[59] Such a presumption is of course much more difficult to maintain for the many commercial databanks that already exist.[60]

Instruments/Patents

I have now arrived at the final pillar of biotechnology law: patents. No legal instrument impacts as profoundly on biotechnology as patent law. This should come as no surprise. Patent is property, and property is the most influential social ordering mechanism known to man. In environmental law, policies of establishing property rights and markets for what previously were 'public goods' is an attempt to redress the 'tragedy of the commons'.[61] Patent law in part is equally designed to deal with this problem of free-riding. Like the other fields of biotechnology law I discussed, biotechnology patent law has to resolve issues of risk, ethics, governance, and instrumental efficiency.

Put simply, a patent is granted for an *invention* (and not for a mere 'discovery'), and provides the right for a period of some 20 years to stop others from making, using or selling the invention, without the permission of the inventor. In order to qualify for a patent, an invention must be 'new', involve 'an inventive step', and be 'capable of industrial application'.

Patents are the life-support machine for the highly research and capital-intensive life science industry. Without patents there will be no outside investors, and without investors no commercial biotech products. So crucial are patents that research decisions in life science companies are based more on the advice of patent lawyers, than on the opinions of their scientists.[62] In a general sense, I believe that patents may serve the public good, for example because they accelerate the development of new pharmaceuticals. However, there is considerable evidence that biotech patents also harbour serious 'risks' to the public interest.

One such risk is that, because a patent is a monopoly, it will actually make business for competitors more difficult. After patents have been granted for DNA sequences and the protein it encodes, a gold-rush has broken out to obtain such patents, especially for the manufacture of drugs. Patent applications are filed by small and large firms, universities and public sector organizations. The US Patent and Trademark Office (US PTO) in 1991 dealt with 4000 patent applications for

partial human DNA sequences. By 1998, this number had risen to over half a million.[63] This is bad news for large, down-stream companies, because this diffusion of ownership over so many actors creates huge transaction costs for the development of commercial products, because licence fees must be paid to different patent-holders. This phenomenon is referred to as 'the tragedy of the anti-commons'.[64]

For the same reasons, biotech patents risk undermining liberty of research. For example, scientists' liberty to carry out research on breast cancer and ovarian cancer has been compromised. This is because fees need to be paid to the patent-holder, *Myriad*, each time the BRCA1 or 2 genes play a role in their research. Basic human rights such as the right to food and the right to health come under threat, because public research programmes have to be abandoned for these reasons.[65]

In the context of today's occasion, I wish to afford special attention to the trend of universities filing biotech patent applications.[66] Where patents serve to monopolize knowledge rather than disseminate it, where they stifle innovation rather than accelerate it, patenting by universities amounts to an affront to their historic mission. The patenting of medical research in universities is also distorting research priorities. Whereas medical schools in universities should focus on medical advancement that produces the greatest benefit to the world population, at present only 10 percent of health research targets the illnesses that make up 90 percent of the global disease burden.[67] The reason for this is simply because there is very little profit in treating, for example, tropical diseases. Between 1975 and 1997, only 13 of 1,200 new drugs marketed were specifically developed to treat tropical diseases, and only four of these were a direct result of pharmaceutical industry research. And should there exist any remaining concern about the creativity and industriousness of my colleagues in academic hospitals and biology departments who in the past worked without the incentive provided by patents, there are reassuring statistics. 70 percent of scientific papers cited in biotechnology patents originated in public universities, compared with only 16.5 percent from the private sector. Universities should adopt transparent policies ensuring that patent protection of their biotechnological inventions is in pursuit of their historic mission. This is to disseminate knowledge, and not to service the global life science industry, whose equally valid mission it is to make profits.[68]

Claims by patent lawyers that patents are 'ethically neutral' is naive at best, and perhaps plainly dishonest. We should therefore now briefly turn to the issue of the ethics of patenting biotechnological inventions.

Most modern patent laws exclude from patentability inventions that are unethical. Within the EU, we find a list of such examples in the Directive on the Legal Protection of Biotechnological Inventions.[69] This list includes processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, and uses of human embryos for industrial or commercial purposes. However, patent offices are ill-suited to make such ethical judgements. They are therefore understandably reluctant to deny patents based on ethical considerations.

In an example of Dutch courage, the Netherlands challenged the validity of the Patent Directive on the basis of its alleged breach of the fundamental right to human dignity.[70] It argued that, to allow isolated elements of the human body to be patented, would be tantamount to reducing living human matter to a mere commodity, and would constitute an assault on the dignity of mankind. It also argued that no informed consent needs to be given by the donor of genetic material, and that there is nothing in the Directive allowing patients to refuse a treatment involving matter obtained by biotechnological means. The Court rejected the Dutch application.

Patent law offers one of the strongest examples of the globalization of law, and the associated legitimacy problems therefore also affect biotech patents. The 1994 Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) establishes enforceable global (minimum) standards of protection and enforcement for patents. It is administered by the WTO. TRIPS has secured that the extended patent protection for biotechnological inventions that Northern American, European and Japanese businesses enjoyed domestically has now spread globally. It has been calculated that, if fully implemented, TRIPS will secure transfer of funds totalling $20 billion plus from developing countries to the information exporting nations of Europe, Northern America and Japan.[71]

The negative potential of the global patentability of biotechnology, which affects hundreds of millions of people now and in the future, again gives rise to questions of global governance. How may we steer patent protection for biotechnological innovations in the right direction? Similar to risk regulation, where I advocated 'democratizing science', the answer appears to reside in 'democratizing intellectual property'.[72] The 39 pharmaceutical companies that marched to the Pretoria

High Court to enforce their patents on AIDS medication in Africa, where more than 17 million people have already died of AIDS, ultimately decided to settle the case. This remarkable turnaround was due *only* to high profile campaigns by NGOs and civil society.

Democratizing intellectual property rights, in this context, is an effective regulatory mechanism for avoiding both 'tragedies of the commons' and 'tragedies of the anti-commons'. For democratization of patent law to work, and such tragedies to be avoided, three conditions must be met, all of which have been pioneered and refined in environmental law. Actors must have access to information so that they can reach an informed opinion; they should be able to participate in decision-making, and have a (limited) right of access to justice.[73] In this process, NGOs have a crucial role to play, and there is no field of law where there is more extensive experience with NGO participation in governance than environmental law.

Conclusion

Over the past two years, my research group has developed an understanding of the core challenges that determine the new field of biotechnology law. Those challenges are in the sphere of risk regulation, genetic governance, ethics and regulatory effectiveness. To an important extent, our insights have been derived from experiences with environmental regulation.

In the years ahead, I will focus attention on turning these insights into concrete proposals for a regulatory regime that unleashes the huge potential of biotechnology, but contains the risks for our universe, and the life it contains.

Acknowledgements

Having come at the end of this lecture, my gratitude for the opportunity to pursue these research themes first of all extends to the vice-chancellor. He supported the idea to host the research group in principle and, no less significant, to release vital research funds at a time of financial squeeze. Special mention I should also wish to make of NWO, who awarded my PIONEER application.

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I thank you for your attention.

References

1. See P. Baldi, *The Shattered Self – The End of Natural Revolution* (Massachusetts: MIT, 2001).
2. Thus, to use a mundane contemporary example, the power of human love appears finally to have conquered the laws of the state of Alabama, which at the beginning of 1999 still outlawed interracial marriages.
3. On 22 June 1633, the accused Galileo, dressed in a white robe of the penitent, in enforcement of the laws of the Holy Catholic and Apostolic Church, abjured as follows: (…) Therefore, wishing to remove from the minds of your Eminencies and of all faithful Christians this vehement suspicion justly conceived against me, I abjure with a sincere heart and unfeigned faith, I curs and detest the said errors and heresies, and generally all and every error and sect contrary to the Holy Catholic Church. And I swear that for the future I will never again say nor assert in speaking or writing such things as may bring upon me similar suspicion; and if I know any heretic, or person suspected of heresy, I will denounce him to this Holy Officer, or to the Inquisitor or Ordinary of the place where I may be. I also swear and promise to adopt and observe entirely all the penances which have been or may be imposed on me by the Holy Office. And if I contravene any of these said promises, protests or oaths (which God forbid!), I submit myself to all the pains and penalties promulgated by the Sacred Canons and other Decrees, general and particular, against such offenders. So help me God and these His Holy Gospels, which I touch with my own hands (…).' For good measure, it ought to be added that Galileo, having risen from his knees, then muttered 'Eppur si muove' (But still it moves). Extract taken from D. Sobel, *Gallileo's Daughter* (London: Fourth Estate, 1999), 291.
4. P. Baldi, note 1 above.
5. Ibid.
6. See J. Habermas, who warns: 'The manipulation of the makeup of the human genome, which is progressively being decoded, and the hopes entertained by certain scientists of soon being able to take evolution in their own hands do, after all, prove the categorical distinction between the subjective and the objective, the naturally grown and the made, as they extend to regions which, up to now, we could not dispose over. What is at stake is a dedifferentiation, through biotechnology, of deep-rooted categorical distinctions which we have as yet, in the description of ourselves, assumed to be invariant. This dedifferentiation might change our ethical self-understanding as a species in a way that could also affect our moral consciousness – the conditions, that is, of nature-like growth which alone allow us to conceive of ourselves of authors of our own lives and as equal members of the moral community. Knowledge of one's own genome being programmed might prove to be disruptive, I suspect, for our assumption that we exist

as a body or, so to speak, "are" our body, and thus may give rise to a novel, curiously asymmetrical type of relationship between persons.' J. Habermas, *Die Zukunft der Menschlichen Natur* (Cambridge: Polity, 2003), 42. For a response to Habermas, see E. Mendieta, 'Communicative Freedom and Genetic Engineering' (2003), 2, *Logos,* 124-140.

7. See C. Tudge, *In Mendel's Footnotes* (London: Vintage, 2000).
8. To be sure, the search for the bases of such genetic exceptionalism does not imply that all (ethical) issues raised by biotechnolgy are new. Quite the contrary, most will be known and in those cases we should build upon existing knowledge and practices. See Murray, who observes: 'From the standpoint of bioethics, research on the human genome presents no completely novel ethical questions, at least for now. This is partly because the nature of new ethical questions, which typically are variants of ethical questions that scholars and others have wrestled with before. This embeddedness of questions in experience with analogous questions means that we do not have to invent every response totally anew, but rather can draw on the history of scholarly analysis that has come before.' T.H. Murray, 'Ethical Issues in Human Genome Resarch' (1991), 5, *The FASEB Journal* 55, 55.
9. See S. Halliday and D.L. Steinberg, 'The Regulated Gene: New Legal Dilemmas', (2004), 12, *Medical Law Review,* 12.
10. Art.2 United Nations Conference on Environment and Development: Convention on Biological Diversity, opened for signature on June 5, 1992 31 I.L.M. 818.
11. See F. Fukuyama, *Our Posthuman Future* (New York: Picador, 2002).
12. Currently, over 800 million people live on the verge of starvation, and a further 1.2 billion subsist on only $1 a day. See United Nations Population Fund, State of the world Population 2001, cha. 2 (2001), published on the Internet at: http://www.unfpa.org/swp/2001/english/ch02.html#2.
13. The belief that such biodiversity loss occurs mainly in biodiversity rich regions (in particular the tropical rainforest) is fundamentally mistaken. In Europe, the number of species deemed by the International Union for the Conservation of Nature (IUCN) to be under threat runs into the hundreds; 42% of mammal species (out of a total of 250), 15% of bird species (total 520), 30% of amphibian species (total 75), 45% of reptile species (total 120), 41% of freshwater fish species (total 190), 12% of butterfly species (total 575) and about 21% of plant species (total 12,500) are now considered to be under threat. See IUCN SPECIES SURVIVAL COMMISSION, *2002 IUCN Red List of threatened species*.
14. Information on the threat of bioterrorism and the EU's response to this threat has been published on the Internet at: http://europa.eu.int/comm/health/ph_threats/Bioterrorisme/bioterrorisme_en.htm.
15. An instructive paper on patenting DNA was published by the Nuffield Council on Bioethics, *The Ethics of Patenting DNA – A Discussion Paper* (London: Nuffield Council on

Bioethics, 2002). This paper is available on the Internet at: http://www.nuffield-bioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf.

16. See M. Warnock, 'What is Natural? And should we care? (2003), 78, *Philosophy,* 445-459.
17. See New Zealand Law Commission Report No. 88, April 2005, *New Issues in Legal Parenthood*, April 2005, Published on the Internet at: http://www.lawcom.govt.nz/Documents/Publications/R88SOP.pdf.
18. M. Hardt and A. Negri, *Empire* (Cambridge: Harvard University Press, 2000), xiv-xv. The connection with the work of Hardt and Negri was made by I. Forbes in *States of Uncertainty: Governing the Empire of Biotechnology*, PSA Annual Conference, University of Leicester, 15-17 April 2003.
19. It has been widely assumed that factual ignorance explains opposition to biotechnology. This also partly underpins Dutch policy towards biotechnology: 'Omdat het lobby-proces zich meer en meer institutionaliseert en professionaliseert, wordt het steeds belangrijker dat er onafhankelijke, geobjectiveerde kennis beschikbaar is.' *Beslissen over Biotechnology*, Wetenschappelijke Raad voor het Regeringsbeleid (Den Haag: Sdu, 2003), 24. This paradigm also appears to have been built into Eurobarometer surveys to reveal the attitude of European citizens towards biotechnology. Discredited by scholars in the field of sociology of science, managers of the Eurobarometer finally conceded that their surveys showed no direct link between knowledge and concern. Rather, the results could be interpreted as suggesting that more knowledge has led to less support. See L. Levidov and C. Marris, 'Science and governance in Europe: lessons from the case of agricultural biotechnology' (2001), 28, *Science and Public Policy,* 345-360, 347.
20. E.O. Wilson, *The Future of Life* (London: Vintage, 2003).
21. See J. Braithwaite and P. Drahos, *Global Business Regulation* (Cambridge: Cambridge University Press, 2003), who support a definition of globalization that relates to the 'intensification of economic, political, social and cultural relations across borders' (p. 8). They add that, 'the more convergent the phenomenon in question, the stronger the globalization. For example, patent systems that move toward the same set of rules are more globalized than those that simply recognize the same basic principles.'
22. For a useful example of such an exercise see for example G. Gaivoronskaia and K.E. Solem, 'Managing Risks in Biotechnology: Can we Learn from Nuclear Power?' (2001), 3, *Journal of Future Studies, Strategic Thinking and Policy,* 33-45.
23. (Decision) risk is a precise technical usage of the term 'risk' to mean a situation under which it is possible to define all possible outcomes and confidently assign a probability to reflect the likelihood of each outcome. (Technological) risk is broad colloquial usage of the term 'risk' to mean the general property of threatening adverse impacts or effects. From: Glossery in A. Stirling, *On Science And Precaution in The Management Of Technological Risk*, Final Report of a project for the EC Forward Studies Unit under the

auspices of the ESTO Network, published on the Internet at: http://www.sussex.ac.uk/Units/gec/gecko/r9e-prc-.htm.

First articulated by U. Beck, social scientists widely refer to advent of a 'Risk Society' at the end of the twentieth century. Risk has become an ordering principle, much in the same way as capital has been so regarded.

24. 'Uncertainty' refers to a situation under which it is possible to define all possible outcomes, but where there is no basis for the confident assigning of probabilities. See 'Glossery' in Stirling, n. 23 above.
25. 'Ignorance' refers to a situation under which it is possible neither to assign probabilities nor even to define all possible outcomes. Ibid.
26. Important literature exists which seeks to explain this curious state of affairs. See D. MacKenzie, *Inventing Accuracy. A historical sociology of nuclear missile guidance*, (Cambridge MA: MIT Press, 1990); S. Funtowicz and J. Ravetz, 'Scientific Uncertainty and Quality Evaluation in Technology Scenarios and R&D Programmes', in *Energy Technologies for Reducing Greenhouse Emissions* (Paris: OECD, 1989); J. Ravetz, 'Three Types of Risk Assessment and the Emergence of Post-Normal Science', in S. Krimsky and D. Golding (eds.), *Social Theories of Risk* (Westport: Prager, 1992), 251-74.

    Hayek, in his famous Nobel acceptance speech, encapsulates much of this later literature in his closing paragraph: 'If man is not to do more harm than good in his efforts to improve the social order, he will have to learn that in this, as in all other fields where essential complexity of an organized kind prevails, he cannot acquire the full knowledge which would make mastery of the events possible. He will therefore have to use what knowledge he can achieve, not to shape the results as the craftsman shapes his handiwork, but rather to cultivate a growth by providing the appropriate environment, in the manner in which the gardener does this for his plants. There is danger in the exuberant feeling of ever growing power which the advance of the physical sciences has engendered and which tempts man to try, 'dizzy with success', to use a characteristic phrase of early communism, to subject not only our natural but also our human environment to the control of a human will. The recognition of the insuperable limits to his knowledge ought indeed to teach the student of society a lesson of humility which should guard him against becoming an accomplice in men's fatal striving to control society-a striving which makes him not only a tyrant over his fellows, but which may well make him the destroyer of a civilization which no brain has designed but which has grown from the free efforts of millions of individuals.' F.A. von Hayek, 'The Pretence of Knowledge' (1989), 79, *American Economic Review* 3-7.
27. See Art. 174(2) EC: 'Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. *It shall be based on the Precautionary Principle* and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter pays (my emphasis).'

28. For example in the preamble of the Convention on Biodiversity of 1992, and in the principles of the Convention on Climate Change of 1992. Aspects of precaution can be found in rules governing international trade, such as the Agreement on Sanitary and Phytosanitary Measures of the WTO and the Cartagena Protocol on Biosafety.
29. See Art. 174(2) EC: 'Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. *It shall be based on the Precautionary Principle* and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter pays (my emphasis).'
30. Case T-13/99, *Pfizer Animal Health SA* v. Council [2002] ECR II-3305. See also the joined BSE cases C-157/96 and C-180/96. The BSE crisis has accelerated the proliferation of the precautionary principle in medicine. In a commentary in *The Lancet*, blood policy specialists Kumanan Wilson of Toronto General Hospital and Maura N. Ricketts of Health Canada argue that: 'The key lesson from this policy-making experience is that lack of definitive evidence should not preclude action for serious potential exposures,' they wrote in support of applying the precautionary principle in medicine. See M. Kaufman, *Washington Post*, August 6, 2004, p. A02. See Editorial Comment Caution required with the Precautionary Principle' in (2000), 356, *The Lancet,* 265, which observes: 'Whose health is being protected by this invocation of the precautionary principle? And who will benefit if and when malaria endemic countries are forced to switch to newer, more expensive insecticides? The answer seems to be that the health of people in poorer countries is being put at a very real risk to protect the citizens of wealthier nations from a theoretical risk.'
31. See Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC (Deliberate Release Directive). Recital 8 states that: '[T]he precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it.' Article 1 provides that: 'In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when:

    - carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community,
    - placing on the market genetically modified organisms as or in products within the Community.'

    Article 4(1) states:

    'Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of

GMOs. GMOs may only be deliberately released or placed on the market in conformity with part B or part C respectively.'

Annex II, entitled 'Principles for the Environmental Risk Assessment' provides: 'In accordance with the precautionary principle, the following general principles should be followed when performing the e.r.a.:

- identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;
- the e.r.a. should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;
- the e.r.a. should be carried out on a case by case basis, meaning that the required information may vary depending on the type of the GMOs concerned, their intended use and the potential receiving environment, taking into account, i.a., GMOs already in the environment;
- if new information on the GMO and its effects on human health or the environment becomes available, the e.r.a. may need to be readdressed in order to:
- determine whether the risk has changed;
- determine whether there is a need for amending the risk management accordingly.'

Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed does not contain an explicit reference to the precautionary principle, which is striking, but implicitly is governed by it given the continued relevance of the Deliberate Release Directive.

Regulation (EC) No. 1830/2003 concerning the Traceability of Food and Feed Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC provides in recital 3: 'Traceability requirements for GMOs should facilitate both the withdrawal of products where unforeseen adverse effects on human health, animal health or the environment, including ecosystems, are established, and the targeting of monitoring to examine potential effects on, in particular, the environment. Traceability should also facilitate the implementation of risk management measures in accordance with the precautionary principle.'

See generally about this new legislation T.F.M. Etty, 'Nieuwe Ronde, Nieuwe Kansen voor GGO's in Europa?' (2004), 10, *Nederlands Tijdschrift voor Europees Recht,* 21-31.

32. This assertion may appear problematic in the case of therapeutic gene manipulations in embryos. Habermas struggles with this question, and observes that in such cases 'the legitimizing force [is drawn from] the well-founded counterfactual assumption of a possible consensus reached with another person who is capable of saying yes or no. The burden of proof is thus shifted to the justification of an anticipated consent that at present cannot be sought (...). In any case, *assumed* consensus can only be invoked for the goal of avoiding evils which are unquestionably extreme and likely to be rejected by all.' See H. Habermas, *The Future of Human Nature* (Cambridge: Policy, 2003), 43.

33. Genetic techniques may help resolve the problem of rejection of transplanted animal tissues. The risks associated with such a procedure are significant, however. There are likely to be dormant viruses incorporated in the genome of the animal, which could only become apparent many generations later. See Editorial 'Halt the Xeno-bandwagon: Xenotransplantation's Risks Make a Moratorium Essential' (1998), *Nature,* 309.
34. Jasanoff, 'Accountability: (No?) Accounting for Expertise' (2003), 30, *Science and Public Policy,* 157-62.
35. J. Atik, 'Democratizing the WTO', *The George Washington International Law Review*, 2001, http://ssrn.com/abstract=250331.
36. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, January 29, 2000, U.N. Doc. UNEP/CBD/ExCOP/1/3, 39, *International Legal Materials* 1027, published on the Internet at: http://www.bodiv.org/biosafety/protocol.asp.
37. See Jasanoff, 'Science and Citizenship: a New Synergy?' (2004), 31, *Science and Public Policy*, 30-34.
38. Arts. 7 and 8.
39. See M.P. Healey, 'Information Based Regulation and International Trade in Genetically Modified Agricultural Products: An Evaluation of the Cartagena Protocol on Biosafety' (2002), 9, *Journal of Law &Policy,* 205-247.
40. The EU regime concerning GMOs essentially revolves around the following instruments:

    - Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Directive 90/220/EEC (Deliberate Release Directive) [2001], OJ 106/1.

    - Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed [2003], OJ 268/1.

    - Regulation (EC) 1830/2003 concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC [2003], OJ 268/24.

    - Regulation (EC) No. 1946/2003 on transboundary movements of genetically modified organisms [2003], OJ 287/1.

    - Regulation (EC) No. 65/2004 Establishing a System for the Development and Assignment of Unique Identifiers for Genetically Modified Organisms [2004], OJ 10/5.
41. [2001], OJ 106/1.
42. See T.K. Hervey, 'Regulation of Genetically Modified Products in a Multi-Level System of Governance: Science or Citizens?' (2001), 10, *Review of Community and International Environmental Law,* 321-328.
43. Art. 23 provides:

    1. Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reas-

sessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory.

The Member State shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public.

The Member State shall immediately inform the Commission and the other Member States of actions taken under this Article and give reasons for its decision, supplying its review of the environmental risk assessment, indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.

2. A decision shall be taken on the matter within 60 days in accordance with the procedure laid down in Article 30(2). For the purpose of calculating the 60 day period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of the Scientific Committee(s) which has/have been consulted shall not be taken into account. The period of time during which the Commission is awaiting the opinion of the Scientific Committee(s) consulted shall not exceed 60 days.

Likewise, the period of time the Council takes to act in accordance with the procedure laid down in Article 30(2) shall not be taken into account.

44. But see C. Joerges, who has published widely on this question, and emphasizes the legitimizing features of commitology. C. Joerges, '"Deliberative Supranationalism" - A Defence', *European Integration online Papers* (EIoP), Vol. 5, No. 8, July 4, 2001; "Deliberative Supranationalism" – Two Defences', *European Law Journal*, Vol. 8, No. 1, 133-151, 2002; C. Joerges, 'Law, Science and the Management of Risks to Health at the National, European and International Level – stories on Baby Dummies, Mad Cows and Hormones in Beef', *Columbia Journal of European Law*, Vol. 7, 1-19, 2001; C. Joerges and E. Vos (eds.), *Eu Committees, Social Regulation, Law and Politics: Social Regulation, Law and Politics* (Oxford: Hart, 1999).
45. This is the comitology procedure laid down in Decision 99/468/EC. In such cases, Arts. 5 and 7 of December 1999, 99/468/EC apply.
46. Unlike its predecessor (Art. 21 of Directive 90/220/EEC), the effect of the procedure referred to in Art. 30(2) is that, where the Committee fails to adopt the Commission's proposal, the Council may not only adopt the proposal by a qualified majority, but may also *reject* it by a qualified majority. In the latter case, the Commission must re-examine the proposal.
47. Case C-6/99, *Greenpeace* v. *Ministère de l'Agriculture et de la Pêche and Others* [2000], ECR I-1651.

48. 10th Recital. in respect of the deliberate release of GMOs for any other purpose than for placing on the market (Part B of the Directive) Art. 9 provides:

1. Member States shall, without prejudice to the provisions of Articles 7 and 25, consult the public and, where appropriate, groups on the proposed deliberate release. In doing so, Member States shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion.

2. Without prejudice to the provisions of Article 25:

- Member States shall make available to the public information on all part B releases of GMOs in their territory;
- the Commission shall make available to the public the information contained in the system of exchange of information pursuant to Article 11.

In respect of the placing on the market of GMOs as or in products (Part C of the Directive) Art. 24 provides:

1. Without prejudice to Article 25, upon receipt of a notification in accordance with Article 13(1), the Commission shall immediately make available to the public the summary referred to in Article 13(2)(h). The Commission shall also make available to the public assessment reports in the case referred to in Article 14(3)(a). The public may make comments to the Commission within 30 days. The Commission shall immediately forward the comments to the competent authorities.

2. Without prejudice to Article 25, for all GMOs which have received written consent for placing on the market or whose placing on the market was rejected as or in products under this Directive, the assessment reports carried out for these GMOs and the opinion(s) of the Scientific Committees consulted shall be made available to the public. For each product, the GMO or GMOs contained therein and the use or uses shall be clearly specified.

Art. 31(3) provides:

Without prejudice to paragraph 2 and point A No 7 of Annex IV,

(a) Member States shall establish public registers in which the location of the release of the GMOs under part B is recorded.

(b) Member States shall also establish registers for recording the location of GMOs grown under part C, inter alia so that the possible effects of such GMOs on the environment may be monitored in accordance with the provisions of Articles 19(3)(f) and 20(1). Without prejudice to such provisions in Articles 19 and 20, the said locations shall:

- be notified to the competent authorities, and
- be made known to the public

in the manner deemed appropriate by the competent authorities and in accordance with national provisions.

See also Art. 7.2, regarding public consultation about use of the differentiated procedure; Art. 8.2. regarding consultation of the public in respect of modifications and/or new information regarding a deliberate release, and Art. 16.3 regarding consultation of the public in respect of criteria and information for specified GMOs.

49. See further Regulation (EC) 1830/2003 concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC, above n. 40.
50. Under these proposed rules, the EU will not fund human embryonic stem cell research in countries where it is forbidden. These guidelines also provide that:
    - stem cells may only be derived from embryos created before 27 June 2002 (which is when Research Framework Programme 6 was adopted);
    - the research will only be funded when no adequate alternative - particularly existing embryo or adult stem cells - exist; the planned work must meet particularly important research objectives.
51. See case C-159/90, *Society for the Protection of the Unborn* [1991] ECR I-4685.
52. The German Embryo Protection law exemplifies this concern. The use of embryonic stem cells is prohibited under German law, explained historically by the atrocities carried out in German concentration camps in the second World War. However, in order to prevent the brain drain of German scientists going abroad to conduct their research and harm to German industry, the German law allows for the importation of embryonic stem-cells. Interestingly given this historical context, most embryonic stem cells are imported from Israel.
53. Adjudicators typically are reluctant to take up such regulatory functions. See for example the case involving a test animal for AIDS research the Opposition Division of the European Patent Office observed: 'As long a claimed invention has a legitimate use, it cannot be the role of the EPO to act as a moral censor and invoke the provisions of Article 53(a) EPC to refuse on ethical ground to grant a patent on legal research and directed to an invention indisputably associated with medical benefits. The technology underlying the present invention is undoubtedly controversial and the subject of intensive discussion in the media and among member of the public. However, there is at present no consensus in Europe[an] society about the desirability or otherwise of this technology, and public opinion is still being formed on this and related matters. It would be presumptuous for the EPO to interfere in this public debate.' [2002], E.P.O. R. 2. See Brownsword, 'Regulating Human Genetics for a New Millennium' (2004), 12, *Medical Law Review,* 14-39 at 28.
54. See Report of the Working Group 'Democratising Expertise and Establishing Scientific Reference Systems', by A. Liberatore (Rapporteur), May 2001, published on the Internet at: http://europa.eu.int/comm/governance/areas/group2/report_en.pdf.
55. Ibid, p. 7.

56. Halliday and Steinberg, n. 9 above at 9.
57. See R.R. Faden and T.L. Beachamp, *A History of Informed Consent* (New York: Oxford University Press,1986); A. Wolf, 'Negotiated Consent: A Negotiated Formula for Trade in Risky Organisms and Chemicals' (2001), 5, *International Negotiation,* 485-521, 488.
58. The term 'biobank' refers to organized collection of biological samples and data associated with them. See A. Cambon-Thomsen, 'The Social and Ethical Issues of Post-Genomic Human Biobanks' (2004), 5, *Nature Reviews Genetics*, 866-73. It has been defined by the UK Human Genetics Commission as: 'Collections of genetic sequence information, or of human tissue from which such information might be derived that are or could be linked to named individuals', Human Genetics Commission *Inside Information*, 2002 at para. 3.3.
59. See R. Chadwick and Berg, 'Solidarity and Equity: New Ethical Framworks for Genetic Databases' (2001), 2, *Nature Reviews Genetics,* 318 at 327: 'it could be argued that one has a duty to facilitate research progress and to provide knowledge that could be crucial to the health of others.'
60. In Iceland, citizens were deemed to participate, unless they explicitly 'opted out' (in respect of health and genealogical data). Specific consent was required for biological samples. The 1998 Icelandic biobank is run by DeCode, a commercial enterprise that enjoys exclusive rights for a period of 12 years.
61. This term was first coined by the biologist Garett Harding in a lecture on population growth. He wrote: 'The rational herdsman concludes that the only sensible course for him to pursue is to add another animal to his herd. And another; and another… But this is the conclusion reached by each and every herdsman sharing a commons. Therein lies the tragedy. Ruin is the destination tower, which all men rush, each pursuing his own best interest in a society that believes in the freedom of the commons. Freedom in commons brings ruin to all.' G. Hardin, 'The Tragedy of the Commons' (1968), 162, *Science,* 1243-1248.
62. G. Dutfield, *Intellectual Property Rights and the Life Science Industries* (Aldershot: Ashgate, 2003), 153.
63. Ibid, 156.
64. See M.A. Heller and R.S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998), 280, *Science,* 698-701. P. Drahos and J. Braithwaite, *Information Feudalism* (New York: The New Press, 1990).
65. In sub-Saharan Africa alone, more than 17 million people have died of AIDS. Anti-retroviral medication has become increasingly effective. And although their price has come down, treatment cost initially was in the range of US$10.000 to US$15.000 per person per year. These exorbitant prices are due mostly due to patent protection of these drugs. For example, the anti-retroviral drug Nevirapine is available from the Brazilian generic manufacturer FarManguinhos at US$0.59 per day. Drug companies

have pursued legal action to enforce their patent rights against South Africa for allowing parallel imports of such cheap drugs to supply to its dying population. See Drahos and Braithwaite, ibid. 5-7.

66. Advies voor het Wetenschaps en Technologiebeleid, *Handelen met Kennis – Universitair Beleid omwille Kennisbenutting*, AWT rapport No. 46, juni 2001.
67. Oxfam, *Cut the Cost: Fatal Side Effects: Medicine Patents Under the Microscope* (Oxford: Oxfam, 2000), quoted in Drahos and Braithwaite, above n. 64 at 189.
68. See G. van Overwalle, 'Academische kennis, Octrooirecht en Ethiek: een Netelige Verkenning' (2003), 13, *Ethische Verkenningen* 8-20. See K.R. Markiewicz, 'Building Fences or Opening Doors: University Patenting and the Pace of Knowledge Exploitation in Industrial Patents', published on the Internet at: http://emlab.berkeley.edu/users/bhhall/others/Markiewicz_InnSem.pdf.
69. Article 6 of the Directive provides:
    1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to order public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
    2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
    (a) processes for cloning human beings;
    (b) processes for modifying the germ line genetic identity of human beings;
    (c) uses of human embryos for industrial or commercial purposes;
    (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.
70. Case 377/98, *Netherlands* v. *Parliament and Council* [2001] ECR I-7079.
71. The World Bank, *Global Economic Prospects and the Developing Countries 2002: Making Trade Work for the World's Poor* (Washington DC: World Bank, 2001).
72. Braithwaite and Drahos, above n. 64 at 189.
73. This is the classical trio found in most modern environmental laws, most notably in the Aarhus Convention (UN/ECE Convention on Access to Information, Public Participation in Decision-Making, and Access to Justice in Environmental Matters 1998), Aarhus (Denmark), 25 June 1998 (entered into force 30 October 2001) (1999) 38 *International Legal,* Materials 3, 517. Tellingly, rather than access to justice, Drahos and Braithwaite include as a third condition that 'one party must not coerce the others'. Drahos and Braithwaite, n. 64 above at 190.