

## Statement in Session V: Impacts on Health and New Technologies

From an ethical point of view there can be no doubt that intellectual property rights (IPRs) and the admissibility of adequate patent protection are legitimate. IPRs and patenting acknowledge the legitimate claims of an author or inventor to his or her product and its commercial exploitation; they foster scientific and economic development, guarantee openness and transparency with respect to scientific developments and their technical applications and, as far as they are sought in the area of agriculture and medicine, especially for pharmaceutical products and medical technology, they serve to improve the provision of food and health care services.

However, the granting of IPRs and patent rights may lead to disturbing ethical consequences. In order to avoid such consequences the legal procedures governing the granting of IPRs and patent rights have always known certain limits. Only inventions not discoveries can be patented – yet only those inventions which are new and show promise of technical applicability as well as commercial value and do not offend against morality and the "ordre public". Besides, the protection of intellectual property as well as the patent itself are limited in their duration and not effective in areas in which welfare has priority, as for example surgery and therapeutic measures in medicine or the cultivation and breeding of plants and animals for the purpose of providing food.

Particular ethical and legal problems arise where the tried legal instruments of IPRs and patenting are applied to scientific and technical areas that are completely new and significantly different from their traditional scope. This is particularly apparent in the life sciences and their application, especially in medicine and notably in the areas of genome research and genetic technology.

The problems that have proved in need of extensive discussion are:

- the distinction between (non patentable) discoveries and (patentable) inventions, especially with a view to the possibility of a "patent on (biological) substances"
- the definition of the criterion of morality and "ordre public", without which the granting of a patent is not possible under current guidelines, especially with a view to reproductive cloning, germ line interventions and eugenic practices etc.
- whether and to what extent living organisms, especially the human body and its parts, can be the subject of IPRs and patents
- whether and to what extent the granting of IPRs and patents limits the freedom of research in the life sciences
- to what extent the granting of IPRs and patents encroaches on the hitherto protected areas of diagnosis and therapy and therefore limits the possibilities for curing diseases
- to what extent the granting of IPRs and patents interferes with the current protection of plant and animal species

- to what extent the granting of IPRs and patents might disadvantage developing countries.

Nearly all of these questions amount to the same problem: how to find a way to enhance the instruments for the safeguarding of moral principles in the areas of IPRs and patents available under current law and achieve transnational regulations that do not discriminate against certain national or regional legal traditions or reward a lack of moral restrictions.

In the following discussion I will concentrate on two points raised in that set of questions, which caused particular controversy in the debate about turning the *European Guideline on the Protection of Biotechnological Inventions* into national law: the granting of a patent on substances for genetic sequences in the context of the question whether (human) life can be patented at all (I) and the consequences of patenting in the area of biotechnology and medicine on research and health care services (II).

## I.

As regards the patenting of genomes, genes, gene sequences or genetically modified organisms the ethical question is this: are legal instruments such as IPRs and patents, which were developed for artefacts of the inanimate world, in conflict with the prohibition against any commercialisation of the human body and thus a violation against human dignity, or – with respect to animals – animal rights and animal protection?

For indeed, the human body and human life are among those conditions without which a human being cannot exist as a moral agent. They therefore must be covered by the protection that humans are due because they have the capacity to be the subject of their actions, i.e. their *dignity*. The protection of that dignity implies that human beings must never be regarded merely as a means to an end or – as the legal profession puts it – must never, at the core of their personhood, be turned into instruments. Besides, the protection of that dignity comprises the basic right to the integrity of one's health and life. From both follows the prohibition against any commercialisation of the human body, as stated in article 21 of the Council of Europe's human rights convention on biomedicine. Article 5 paragraph 1 consideration 16 of the *European Guideline* formulates the consensus that "the human body in all the phases of its development, including the germ cells, the mere discovery of one of its parts or products, including the sequence or parts of the sequence of a human gene cannot be patented".

Special problems arise with respect to the human genome and its parts. For their genes and gene sequences are not peculiar to human beings. They are all the result of our evolution and many are shared with other organisms. Peculiar to human beings is the combination of these genes and gene sequences in our specific and

individual genomes. Because of their importance for the human organism they are the good that is to be protected. But their parts are covered by that protection only inasmuch as they are part of that genome, not as such.

As far as genes and gene sequences are concerned we have to consider that what is the characteristic and fundamental aspect of their function is not their chemical components, i.e. the four nucleotides, but their combination, or rather the "information" contained in that combination. That distinguishes them from traditional patents on other substances, difficult as it is to draw that distinction.

This is apparent in article 5 paragraph 3 of the *European Guideline* which allows the granting of a patent on substances for genetic sequences. Is that not a contradiction to paragraph 1 which, as we have already seen, prohibits the patenting of (parts of) the human body?

Certainly, a first answer to that question might point out that the granting of a patent does not imply any property rights on the products but only a claim to the commercial exploitation of the *procedure* from which they result. Thus it is not sufficient that there is a product that also occurs naturally; there must also be a procedure that leads to its production or includes its use. Under the traditional rules, the mere discovery of a sequence would not be a sufficient basis to claim a patent.

But – is the "identification, purification, determination and proliferation outside the human body" a procedure that turns the whole process into an *invention* and distinguishes it from a *discovery*? According to Hegel (Philosophy of Law § 41), an invention is the intellectual property of its author because it is an expression of the author's creativity. Now, is the identification of the mutations leading to a form of breast cancer – as in the Myriad Corporation's patent on the BRAC 1 and BRAC 2 genes – even without the identification and production of the relevant proteins sufficient to count as an invention? Is it enough to point to the use and commercial value of the genetic test that is based on it?

In Consideration 21 the *European Guideline* explicitly states that novelty, inventive action and commercial applicability are to be preserved as criteria for the granting of a patent. Consideration 24 specifies that commercial applicability requires that it must be stated "which protein or part of a protein is produced and what function it fulfils". Critics of this regulation point out that the cloning of a genetic sequence and the mere analysing of its function are not sufficient to fulfil the criteria; that these criteria are only part of the (legally non-binding) considerations anyway; and that the regulation does not bridge the gap between the European regulations and those in US patent law.

However, even if the traditional criteria for patenting are applied without restrictions further ethical problems remain. For unlike traditional patents on substances

patents on genetic sequences do not protect a chemical substance and its synthesis but an information and its commercially exploitable function. The "information" contained in biological and especially genetic material, however, is of richer content than its identification and the description of one or more of its functions suggests. The ethical problem that arises is this: the granting of a patent that covers *all* the information contained in a certain sequence rewards the inventor more than is due and puts researchers who work on that sequence later into a position of dependency and unduly restricts their patent claims. This could also weaken the principle – held up by HUGO as well as in the Clinton/Blair declaration – that the knowledge which results from the sequencing of the human genome must be accessible to all researchers. Besides, any restrictions on access to that knowledge would violate the personal rights and the right to self-determination of everyone. If a relevant part of the sequences in question were the subject of unduly restrictive patents, then the commercial exploitation of the knowledge of the human genome by the pharmaceutical industry, let alone small start-up companies, would be unduly restricted as a result.

Thus we need a solution, both at the level of the law as well as the level of its application, which respects the ethical considerations that have traditionally governed the granting of patents. Voluntary foregoing of patents on genetic sequences can help, but they cannot substitute firm legal regulations.

## II.

I will briefly address a second complex of ethical concerns connected with the questions discussed so far: the right to freedom of research and the right of the individual and the corresponding duty of the state to adequate health care services.

If – as is the case in the German Basic Law – one regards the freedom of research as a fundamental right of such weight that it can only be restricted in a conflict with other fundamental rights then the legitimate protection of an invention must take second place to the protection of the freedom of research. The German Constitutional Court has upheld that principle in its judgments and confirmed the rule that existing patents cannot exclude or restrict intended research. The Court states that “unrestricted protection of the patent is not justified because of the freedom of research and the social obligation which goes with the ownership of property where the further development of technology would be impeded ... It would contravene the purposes of patent law if experiments were to be excluded that served research and the further development of technology (1<sup>st</sup> Senate of the German Constitutional Court 1864/95 of 10 May, 2000, paragraph 28).” Naturally, later commercial exploitation of such research must comply with existing patent rights. The ethical considerations that are relevant in view of the freedom of research also require an effective legal base.

This is even more true if the research serves the improvement of health care services and thus touches a fundamental good which led even traditional patent law to exclude the possibility of patents on surgical or therapeutic measures. Certainly, in view of the high stakes played in the development of pharmaceuticals these days the invention of a new combination of therapeutically effective substances must be protected in a way which allows its successful commercial exploitation. On the other hand, such commercial considerations must not outweigh necessary measures of health care provision. Forced licences are a way out here but cannot be regarded as a general solution. Further legal regulations are required and demanded by the German and world organisations of physicians.

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The development of the life sciences has turned life into the subject of technical manipulations far beyond what we knew from plant and animal breeding or medicine. This suggests the application of IPRs and patents in this area. As the discussion has shown the ethical problems that arise can be solved using the criteria and instruments contained in traditional patent law, provided they are adapted to the special requirements of living organisms. This is true particularly for any equivalent of the so-called “patent on substances” and its scope. The solutions hinted at in the *European Guideline* need further development. Given that general norms in patent law are of limited reach this must be borne out by a strict practice of granting or revoking such patents. In addition, further work is needed to reduce the gap between European and international regulations.