

Patents on animals and plants

A contribution to discussion



Swiss Ethics Committee on Non-human
Gene Technology

Protection of intellectual property in biotechnology: ethical considerations in the "patenting" of animals and plants

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I Patents on animals and plants

1 Outline of the problem

The currently applicable regulations on patenting exclude the patenting of plant varieties and animal species. Patents on animals and plants are permissible. The possibility of patenting inventions derived from living organisms has been the subject of public controversy for some time. In the run-up to the public consultation on the revision of the patent law, the Swiss Ethics Committee for Non-hu-

The reason patent law excluded plant varieties and animal breeds¹ from patenting was that the techniques and results of traditional breeding methods were not considered to be sufficiently repeatable to deserve access to the protection of a patent. An independent system of plant variety protection was set up to protect plant varieties. However, a technique that does not involve a single plant variety or a single animal breeds can be patented. This construction renders patents on animals and plants generally permissible, although its logic is not completely convincing and, because of the associated effects, it has prompted considerable controversy.

The permissibility of patents on inventions related to living things has long been a cause of public controversy. In addition, there seems to be an impression that – as a result of Switzerland's participation in the international patenting system and of rapid scientific development focusing on immediate interests – continuous tailoring of the patent regulations to new conditions takes place, without the accompanying ethical and social aspects of such development being adequately discussed. Against the background of the integration of Switzerland into the international patent system through a series of patent agreements, the ECNH finds it necessary and important to provide an ethical critique of patent-

man Gene Technology (ECNH) has therefore taken on the task of summarising the arguments raised in the public arena and presenting its own preliminary considerations for discussion. The ECNH thereby hopes to contribute to the debate on the "patenting of living things" and in particular to the discussion of the ethical aspects of patenting.

Federal Law on Patents for Inventions (Patent Law)

Article 1a:

Patentable inventions: special cases

No patents for inventions are allocated for plant varieties or animal breeds or in general for biological techniques for breeding plants and animals; however, microbiological techniques and their products are patentable.

Article 2:

Disqualification from patenting

The following are disqualified from patenting:

- a. Inventions the use of which would contravene public order or morality;
- b. Surgical, therapeutic or diagnostic techniques that are applied to the human or animal body.

¹ It should be noted that the original German version of Article 1a of the Patent Law of 25 June 1954 refers to animal species (Tierarten), instead of the more correct animal breeds (Tierrassen). To be systematically correct this translation uses animal breeds throughout.

ing within the national framework and supported by the provisions of the constitution. Even if the legally binding regulations are only applicable in Switzerland, the way in which patenting is legitimated and discussed by the public here has more far-reaching effects.

The trigger for the revision of the patent law currently underway is a parliamentary motion² requesting the Federal Council to align Swiss patent law with the European Biotechnology Directive (98/44/EC) of the European Council and Parliament of 1998. The patent protection of biotechnological inventions should be made explicit, and at the same time framework conditions formulated under which such protection may be conferred or avoided. The reservations concerning "public order" and "morality" are here made concrete through the exemplary listing of inventions excepted from patent protection. A revision of the law will undoubtedly help to clarify the area under regulation, which is currently riddled with uncertainties. A broad public consultation of the draft legislation is planned for the end of 2001/beginning of 2002.

² 98.3243 (Leumann Motion, 10 June 1998): Revision of the Patent Law.

The Swiss Ethics Committee on Non-human Gene Technology (ECNH):

ECNH has the task of advising the Federal Council and other authorities on ethical questions of non-human gene and biotechnology. It is concerned with ensuring that respect is given to the issues of the dignity of creation, the security of people and the environment, and the sustainability and conservation of biological diversity. In addition to its advisory function, one of its key tasks is public information work, providing information on questions and themes it handles, and encouraging the public discussion of ethical questions of biotechnology.



2. Development of the discourse and establishment of goals

The starting point for the present discussion paper is the dominant consensus within the ECNH: that intellectual efforts are in principle worthy of protection in the area of biotechnology, although opinions are divided on the permissibility of the "patenting" of living things. On the basis of this consensus the ECNH has drafted a model of an "inventor's privilege", which will be introduced below. The aim of the ECNH is to develop the ethical principles and prerequisites for a system of protection for intellectual property that will realise the interests of inventors in the sole use of their invention, but will avoid the problematic effects that arose through the "patenting" of living things.

The proposed new concept does not call patenting into question as such, but rather the attempts to apply the system of patenting nonliving materials — things and products — to living organisms, thereby making non-living material and living things simply equivalent. The legal question of whether the desired revision of the patent law can integrate the "invention protection model" that was drafted by the ECNH and focused on the patenting of living things, or whether the model requires its own specialised regulation for implementation, is deliberately left open. The draft of a protection system presented here is expressly not linked to patent law, but aims in the first instance to formulate the requirements and prerequisites of an "inventor's privilege". It considers only the ethical requirements that the ECNH makes of the protection of intellectual property in the form of animals and plants. Whether the ethical requirements are compatible with the current patent system or need a new *sui generis* system is not at the forefront of this discussion. Either approach could conceivably formulate ways to implement the requirements. Whether some of the problems outlined below, e.g. in research, call less for modification than for a new interpretation of the law, also needs to be clarified.

Following the introduction of the protection model, various aspects of the patent system and the associated debate will be considered. Next the conceptual suitability of the current patent system for inventions in connection with living things will be

The explanations are concerned solely with the discussion of patents on animals and plants. Aspects affecting the patenting of genes, gene sequences, cells, micro-organisms and so on are largely excluded. The ECNH is nevertheless conscious that there are ethical issues in these areas too. A study focusing specifically on these questions has been commissioned and will be used by the ECNH as a working basis. Since the themes in this area cannot be separated into human and non-human domains, this is one of the problem areas that can most sensibly be considered in collaboration with the newly established National Ethics Committee for Human Medicine.

detailed, before the impact of the patenting of living things is discussed from an ethical point of view. The arguments given document the concerns and considerations of the "patenting" of living things considered so far by the ECNH in its ongoing discussion. Engagement with these issues has enabled the ECNH to sketch the model of «inventor's privilege" in which we believe the issue of the "patenting" of living things may be treated more appropriately, and open it up to discussion. A first draft of the model and the preceding considerations was discussed by experts and lay people at a public event organised by the ECNH at the University of Fribourg in May 2001. The results of this discussion are integrated into the present paper.

II Protection of inventions involving non-human multicellular living organisms – a model as a contribution to discussion

- 1 The protection of inventions involving non-human multicellular living organisms is ethically permitted, under the following conditions:
- 2 The protection applies to procedures for the creation of physiological capacities or pathological modifications of living organisms, identified by species or variety. The intended capacities should be precisely described. The protection also extends to the described capacities in the progeny.
- 3 The ethical and legal regulations which the intended procedure must satisfy include the principle of the dignity of creation, sustainability, the requirement for novelty, the quality of the invention, and the commercial utility, i.e. unlimited repeatability.
- 4 The protection guarantees the right to exclusive commercial use of the procedure that leads to the described capacity, for the duration of time set by the general patent law.
 - 5.1 The agricultural privilege and the breeder's privilege are respected in their entirety.
 - 5.2 Basic research is not hampered.
 - 5.3 Global food security is not impaired, and no monopolies arise which cannot be justified by development and business ethics.
 - 5.4 Social acceptability is ensured, and in particular no ethically unacceptable dependencies are created.
 - 5.5 The aims of the Convention on Biological Diversity will be adhered to. This includes following the principle of benefit-sharing (fair compensation where appropriate; agreements on technology transfer and research collaborations, certificate of origin upon registration).
- 5 The guarantee of protection is further tied to the following conditions:

In terms of item 2, it should be noted that the ECNH is conscious that a capacity cannot be protected independently of the organism in which it occurs. Its recommendation is based on an expanded understanding of "procedure", which also includes the possible transmission of a "function" to the progeny.

In terms of the conditions under item 5, especially 5.2 ff., it should be noted that the ECNH is not suggesting that the issues of world nutrition or the just distribution of and free access to genetic resources can be solved by modification of the patent law alone. The ethical issues arise not only within the framework of a patenting system, but require far-reaching measures at the level of development politics. Coherence of the various political areas is undoubtedly essential.

A justifiable objection to the conditions mentioned under item 5 is that many of the effects of a patent cannot be conclusively evaluated at the time of the registration. A form of monitoring should be devised that would allow a previously made decision to be re-examined if unacceptable consequences result, and the patent to be annulled.

Food security, mentioned under 5.3, requires further discussion and clearer definition, as does the issue of patents on plants and animals that form actual food resources.

The dependencies mentioned under item 5.4 include not just monopolies, but all forms of power concentration. There is a need for greater clarity here about the point of restrictions imposed on damaging monopolies.



III Ethical aspects of the current system of patenting animals and plants

The system of patenting was developed as a compromise between divergent interests. On one side are the interests of the inventor in having exclusive use of intellectual property and thereby receiving financial recompense for the investment in research, and in making a profit. On the other side is the interest of society in making the use of inventions freely available. This system of balancing interests was developed to cover inventions involving non-living material.

The engagement with the ethical aspects of patenting living things has raised many questions which have not yet been conclusively answered in public discourse. Many aspects have so far received too little consideration. The current patent system relies heavily on conventions, which by their nature as "agreements" are open to logical and argumentative criticism. The remaining inconsistencies in this discussion paper may thus reflect the contradictions inherent in the current patent system. Among these is the (rightly) contentious acceptance of the equivalent treatment of non-living material and living organisms. A first step is to clarify the question of whether the currently valid patent system is also conceptually suitable for inventions involving living things, and under which conditions or restrictions. Should the system itself prove to be appropriate, a second step is to clarify whether "patents on life" provoke ethical issues by virtue of their effects. The following discussion is primarily concerned with these two levels.

The conferral of a patent does not necessarily mean that its exercise, that is the commercial use, is permitted. Commercial use is considered under current laws such as the Animal Protection Law or the Law on Foodstuffs.

1 Evaluation of the conceptual suitability of patenting

The question here is whether the patent system, developed as it was for inventions involving non-living material, can in principle be extrapolated to cover inventions involving living organisms. It must be decided whether the model proposed by the ECNH is to be understood as the direct patenting of living organisms, or patenting in the sense of the protection of a procedure. It must also be decided whether the equivalent treatment of living organisms and non-living material is permissible in terms of patenting or whether a relevant distinction excludes such equivalent treatment, and therefore the use of the patent system to cover living organisms.

1.1. Novelty and repeatability as prerequisites for patenting

In order for an invention to be granted a patent, the invention must be new, that is not have been made known either verbally or in writing, and must not be part of accepted practice. Second, the invention must be of inventive use. An activity is considered as inventive when it is "not obvious". This is evaluated by the patent expert according to the criteria of "standard expertise". Whether the invention was made accidentally or on purpose is considered ir-

relevant to whether it qualifies as a patentable invention. Third, the invention must be of commercial utility, i.e. useful. The requirement for commercial utility implies that the procedure must be repeatable.

The requirement for novelty. The quality of novelty usually consists of the bit-by-bit modification of what is already known. The understanding of what is known and what is new changes over the course of time and with changes in technology and knowledge. It follows that "novelty" must be evaluated in comparison with what already exists. When does a modification of a product or a procedure acquire the quality of "novelty" in the sense of patent law? Is there a difference between the modification of non-living material (e.g. modification of a machine, change of its function) and the modification of a living organism (deletion, exchange or insertion of genes) in terms of the quality of novelty? A relevant point raised in the public discussion is the conviction that living things do not have any first inventor and therefore from the outset they fail to fulfil the requirement for novelty. This argument is countered by one that says that this also applies to all non-living substances, and also that it is not the living organism but an invention (change of function, procedure) "embodied" in the living organism, that is under patent. We will return below to the discussion of the distinction between patentable inventions ("ideas") and patentable "embodiments of an idea".

The requirement for repeatability. For a procedure to be patentable it must be clear and repeatable by experts. Can a procedure involving living organisms fulfil these technical requirements for patentability? One argument that has been brought out in the public discussion is that genetically produced living things, even when they are always produced through the same procedure, remain the products of chance. Products that are made on the basis of an invention using non-living material, e.g. light bulbs, are by contrast always identical in their characteristics. The procedure is certainly repeatable in both living organisms and non-living material. The result, which is also covered by the patent, is however only repeatable in the case of non-living material. And in considering whether the results are repeatable in the case of living things,

the general instability of gene-technological modifications in living things must be borne in mind. This model therefore sees a relevant difference between inventions based on living organisms and those based on non-living material.

It seems that neither concept – that of novelty and that of repeatability – can be extrapolated to inventions derived from living organisms without further examination. A closer systematic and theoretical examination of these concepts in terms of their applicability to living organisms is urgent, but has not yet been carried out. The ECNH calls for the protection of procedures to be restricted to a specified function or capacity in an animal or plant, reflecting that a procedure (including what it produces) cannot be repeated in the same way in living things as in non-living material.

1.2 Distinction between "idea" and "embodiment of an idea"

According to conventional understanding, at the heart of the patent is an intellectual achievement: an idea, for example, or a procedure. The patent confers protection on an idea, that is on commercially valuable knowledge. It is not the machine or the living organism that is "patented", but the idea that is "embodied" in the machine or living organism. In this understanding, the question of whether an idea concerns non-living material or a living thing is not ethically relevant. The concept is clear from the following equation: a procedure is a procedure, whether in a machine or a person.

The continuing discussion of the patenting of living organisms counters this point of view by saying that an idea cannot be realised in the absence of a substrate, but is always expressed materially. Even when patent protection is primarily concerned with an idea on which the procedure is based, it always affects the product of the procedure as well. Patent protection on the procedure is of no use to the inventor if an exclusive right of use is not claimed on the result. Living things can, however, reproduce themselves independently. According to previous interpretation of the patent law, patent protection also covers all the progeny of a living organism in which the same function is expressed. Considering

patents on living things, the effect in the light of this concept is a massive extension in the protected rights of use. The purchaser of a patented living organism may not breed from it without the agreement of the patent owner. Despite having ownership of an animal or plant, therefore, the owner does not possess one of the essential characteristics of the living organism: its reproductive ability. Making an idea concrete in non-living material, or alternatively in a living organism, cannot therefore be considered equivalent.

The distinction between "idea" and "embodiment of an idea" does not seem to help solve the problem that results from making living organisms and the traditional objects of patent law equivalent in terms of patenting. An examination is needed of whether protection of the – precisely defined – function, as suggested by the ECNH in its model, would be more appropriate.

1.3. The dignity of creation

The dignity of creation – however contested its power or scope of validity – is a fundamental of the constitution that must be taken into consideration. Even if the material or a living organism is understood solely as the "vehicle" for the realisation of an idea, in terms of the dignity of creation there remain questions about the extent to which the instrumentalisation of living organisms can be permitted.

Instrumentalisation. Every farm animal, and even more so every crop plant, is to some extent instrumentalised by human beings, i.e. reduced to being used as a means. Nevertheless, in accordance with the spirit of the Federal Constitution, every living thing exists primarily for its own sake even within an environment structured by human beings. Impermissible instrumentalisation is therefore a procedure by which an animal or a plant is no longer conceived of as an autonomous living being, but solely in terms of its utility. Of major importance to an ethical judgement of animal and plant use is the effect of instrumentalisation on the respect accorded to the wellbeing of the affected animals and plants. The ECNH is conscious that there exist significant differences in the requirements for the

treatment of animals and plants, and points to other studies that have been carried out in this area.

Many living organisms are produced, bred, kept and used under unsuitable conditions, quite independent of the problem of patenting. Increased respect of animals and plants will thus not be achieved simply by forbidding patenting. It should however be borne in mind that patenting may contribute to an increasing understanding of animals and plants solely as resources in the service of people and in terms of their exploitability and economic utility. The resulting detrimental effect on the careful, considerate and respectful treatment of nature needs to be countered appropriately.

Patents and property. What about the extent of the right of disposal on the basis of patents or of property? When discussing the "patentability" of living things it must be remembered that another right of disposal over living things, that is property right, is generally accepted within our society. The ethical discussion of whether or to what extent it is permissible to exercise exclusive right over natural resources, earth and soil, animals and plants, and to consider them as property, cannot be pursued here. The question to be answered is whether patenting exceeds the right of disposal over property and if so, whether this extension is ethically acceptable. Within the ECNH two different positions are represented.

On the one hand it is argued that patent right impairs the dignity of creation to a greater extent than does property right. Property right, applied to plants that are not covered by patent, applies to both the plants and to their progeny. But if someone buys a patented plant, the propagation of the plant is not permitted without the agreement of the patent holder.

Patent protection thus covers the progeny of the patented plant. A patent owner possesses further rights over a fundamental characteristic of the plant, that is its reproductive ability, even though she or he no longer owns the plant itself.

On the other hand, the opinion has been put forward that ownership confers a much more extensive right over living things than does patent right. A property owner can use a plant as she or he de-

sires; it can be destroyed or sold. A greater right of disposal is also conferred over animals, and an exclusive right of use. By contrast, patent protection gives the owner of the patent only a limited right to the use of an idea. From the point of registration at the patent office a 20-year protection against imitation is guaranteed. If someone wishes to use the technique commercially, a license from the patent owner is required. A patent guarantees a time-limited and territorially restricted right to forbid third parties from using the non-material object of the patented invention for commercial purposes. The patent does not, however, confer the right to use the invention in reality. The possibility of its use is determined by other existing legal regulations (for example the Drug Law, the Animal Protection Law etc.). In order for the patent owner to have control of an idea, the patent protection must also cover every other living thing in which this idea is embodied. There remains a fundamental difference between property and patent right in that the reproduction of living things cannot be owned, but by this interpretation the difference specifically in terms of power over the plants is of no ethical relevance. So a right of disposal obtained through a patent over living things is more restricted than one associated with property. If respect for the dignity of creation can be compatible with justifying ownership of living organisms, then it follows that the dignity of creation is no more impaired by patent law than by property law.

1.4. The "slippery slope" argument

Procedures that can be used on animals are in general also usable on humans. Techniques that can be applied to animals can usually also be applied to humans. Procedures that can be used on mammals can also be used on the "mammalian" human being. There is therefore a widespread fear that the ability to patent living things is the top of a slippery slope leading headlong to the issuing of patents on human beings. The "slippery slope" argument is based on the concern that once the first step is allowed, the next must inevitably follow. According to this argument, the truly reprehensible thing about patenting living organisms is that it entails the possibility of patenting people.

To use such a "slippery slope" argument against the patenting of living things, it must not merely be that such a development is conceivable. It must first be shown that it is probable that such a development will occur, and second, that it is unlikely that countermeasures will be successful. Some members of the ECNH are of the opinion that there is no plausible "slippery slope" argument against the patenting of living things. Other members point out that there have already been some patent applications by research projects on mammalian embryos, which specifically include, or at least do not specifically exclude, human embryos. These members therefore give greater weight to the "slippery slope" argument.

We should state here that the version of the model of protection proposed by the ECNH does not exclude the "living human organism" from being the object of protection claims. It should be specified that the human being at all stages of development, as well as procedures that injure its dignity, are excluded from patentability as a matter of principle.

1.5. "Public order" and "morality"

The general clauses of the "public order" and "morality", which are integrated into patent law, should already have made possible the inclusion of over-arching ethical considerations. It is here that ethics are directly addressed in patent law. What meaning do these expressions have for "patenting" living organisms?

"Public order". According to widespread jurisprudence and legal precedent, an offence against the "public order" occurs only if the use of the invention offends against the fundamental principles of legal order. This means all norms providing the principles for the realisation of state, economic and social life. An offence against the "public order" thus only occurs, by current understanding, if the use offends against the law or guidelines. These restrictions are based on the general interest, because regulations at the legislative level can be altered within a relatively short time frame, and because a patent does not concede the right to use an invention but only the right to prevent third parties using or imitating it. In the opinion of the ECNH, as has

already been stated, if a biotechnological invention, e.g. a specific function, is expressed in a transgenic animal whose production cannot be justified as ethical following a comprehensive, carefully carried out evaluation, then it fails to respect the dignity of creation³ If the constitutional principle of the dignity of creation is taken as fundamental, we must also assume that such an invention should be excluded from patenting on the grounds of "public order".

"Morality". The legal understanding of the term "morality" is a mutable one. If a patent is to be denied, the commercial use of the invention is not permitted, and this ban on its use stems from the fundamental principles of legal order. So according to this legal understanding it is not impossible to declare something as offending against "morality" and thus not patentable, and at the same time to allow its sale. From the point of view of "morality" it should be noted that to treat living organisms like non-living material conflicts with many people's basic convictions. A change of mind has taken place here that is reflected in such things as the political shift in the legal status of animals and the acceptance of principles such as the "dignity of creation" in the Federal Constitution. The insight that living things deserve respect in and of themselves has led to an increasing sensitisation and critical attention towards areas where regard and respect for the intrinsic value of the living thing are, or appear to be, disregarded.

The terms "public order" and "morality" introduce ethical criteria into the patent system. As so far interpreted, these two ethical terms apply to people. The changed relationship between people and animals must however be discussed in terms of "morality". The discussion to date indicates that these two general clauses are not adequate for a fundamental consideration of the dignity of creation in terms of the patenting of living things.

³ For the evaluation of research using animals, the involved interests on the sides of both humans and animals must be identified, estimated and weighed up against each other. If the animal interest is considered to outweigh the human, permission for the performance of the research is not given (see the publication «Die Würde der Tieres», available in German, French and Italian, ECNH and EKTIV; Berne, February 2001).

2 Evaluation of the impacts of patenting

The central question to be examined here is whether the impacts of patenting infringe ethical limits, and to what degree these limits counter the justification for the ability to patent inventions based on living things.

2.1. Impact on the dignity of creation

Under item 1.3 the question of whether the patenting procedure in itself affects the dignity of creation was discussed. It is necessary here to examine whether the effects of the exclusive rights to the use of an idea, "embodied" in a living thing which is therefore included in the exclusive right to use, is compatible with the dignity of creation. The ECNH is particularly concerned with the effect that the "patenting" of animals and plants has on our understanding and treatment of living things. The equivalence of living things and inanimate objects within the framework of the current patent law is problematic, in that it increases the tendency to look on animals as goods and products rather than living beings with their own intrinsic value; a tendency which cannot be blamed solely on patenting, but whose origins are to be found in modern battery farming methods and techniques of animal production.

2.2. Impact on research and knowledge transfer

Traditionally the patenting system played an important role in encouraging research. Patents made possible a degree of harmonisation between two structurally divergent interests: on the one side the financial interests of the inventor in the exclusive use of his or her invention, and on the other the interests of society in using scientific progress for its own benefit.

The systematic application of patents is today no longer confined to industry, largely the pharmaceutical and agronomic industries. Patents are increasingly being used by universities and by general public laboratories carrying out basic research. The

rapid increase in the number of patents has fundamentally changed the practice of research and the spread of knowledge. In the academic environment, where previously there was a general free exchange of information and research materials, more restrictive practices have been introduced. Increasingly, the use of basic materials or their components in research involves claims for compensation for intellectual property, hindering the researchers' work. Increasingly also, the universities want to profit from their work. Developments in the United States indicate that university administrations frequently prevent researchers from continuing former, more liberal practices. The pressure to patent is proving to be a barrier to free communication in the research community. Publications are delayed by months, and this delay is already apparent in connection with the mere possibility of patenting. Contracts, known as material transfer agreements (MTA), protect subsequent patents. Since not every researcher can "create" the starting materials (e.g. specific antibodies, genes, animals and plants with defined characteristics) for a particular research project him or herself but must "buy" these materials, a complicated system of contracts has arisen to relate the provision of materials to the use of the possible results of patentable inventions. Often it is the providers of "research materials" to whom all patent rights must be conceded. The fact that certain results then may not be published at all, if it does not suit the owner of the patent, is particularly problematic. The transparency apparently guaranteed by the patent system is thus turned into its exact opposite. A suggestion worth considering is the development of a model MTA contract, which would be widely recognised and at the same time would protect the interests of the supplier as well as those pursuing the research.

It is also apparent that an increasing number of patented inventions are no longer of public significance, but are stages in the scientific research process. Should such stages be covered by patent claims, they would become additional hurdles associated with growing costs for research. If the criterion of industrial utility of patented inventions no longer plays a major role in the patent system, patenting will retard research. This by itself is still not an argument for completely rejecting the protection of biotechnological inventions by patenting.

It is, however, a reason to evaluate rigorously the patentability of such inventions. This has less to do with a change or reformulation of the legal regulations, and more with a deeper discussion of how the law is interpreted. In this context we should first define more precisely the juridical and social function provided by the system of protection of intellectual achievements in biotechnology. The patent was developed as an alternative to manufacturing secrecy. It is a fundamental contradiction of this idea if it becomes an instrument for maintaining secrecy and blocking the free transfer of knowledge.

The generalisation of patents in the life sciences has another, more indirect effect. It influences the selection of topics for research that universities consider worth doing. Some academic research, for example in biomedicine, is clearly basic research because of the type of questions it asks and the methods it uses. This research however may also have practical use, for which patenting would be a possibility. If the tendency to favour patentable research continues, there is a risk that the aims of true basic research will be neglected. This could in turn lead to a withdrawal of support for basic research on the part of political decision-makers and the general public.

For the regulation or prevention of socially undesirable research aims or abuses, patents are clearly very limited instruments. In the attempt to harmonise the divergent social interests that are involved, it must be remembered that a consequent rejection of protection claims in such cases would not lead prevent the research, but would rather remove it from public control. As already emphasised elsewhere, the solution must be sought in a combination of measures.

2.3. Impact on social and development policy

The tendency to apply for the broadest possible patents must also be considered in terms of the consequences for social and development policy. A variety of aspects must be considered here:

Traditional knowledge and "biopiracy". In development policy, "biopiracy" presents an important

issue in the debate between the highly industrialised and less or not at all industrialised countries, and also indigenous peoples. Many genetic resources, especially in food crops and plant pharmaceuticals, originate in the southern hemisphere while providing researchers and scientists of the northern hemisphere with "raw materials" for their inventions. According to the prevailing concept, patenting is possible even when, for example, the therapeutic effects of plants are traditional knowledge. The question arises of whether indigenous peoples have rights that would prevent the patenting of effects and functions that already form part of traditional knowledge. Another question is how this indigenous knowledge can be better protected, and compensated. A starting point is perhaps provided by equality between inventors and stakeholders in biological material.

Agricultural privilege. While repeated cropping, that is acquiring seeds from the harvest, has largely lost its significance in the industrialised countries, it continues to play an important and sometimes vital role in the non-industrialised countries in terms of food security and the commercial autonomy of farming communities. It is a centuries-old practice that has a central place in the social and cultural activities of many of these countries. The continued possibility of repeated cropping must therefore be ensured. In the context of ensuring agricultural privilege consideration must also be given to issues of liability, such as how to avoid farmers being made responsible, in other words liable, for the airborne spread of pollen and "contamination".

Breeder exemption. The breeding of new plant varieties and animal breeds has an influence on the free exchangeability of genetic resources. Different varieties or breeds can be crossed until a new variety or breed with the desired characteristics is produced. Genetic resources should therefore remain accessible to all.

Food security. The production of adequate food, and access to the means of its production, should be ensured and facilitated. No practice should restrict this access.

Understanding of ownership. Different understandings of property in different cultures, for ex-

ample where community rights are privileged over individual rights, should be respected. Community invention rights should be made possible.

Power distribution. As monopolies are the expression of one-sided power distribution and thereby endanger commercial competition and social stability, protection rights that are precisely delimited should be preferred to those that are more broadly interpreted (e.g. by patents).

It has already been established in other contexts that fundamental development policy problems in the relationship between the industrialised and less or not industrialised countries, and the impacts on environmental and research policy, cannot be solved solely by means of the various aspects of patent law. The careful examination of accompanying measures on other levels is clearly essential.

2.4. Ecological effects

Protection of species diversity. The protection of inventions concerning seeds could lead to an increase in monopolisation and thus to a reduction in species diversity, notably to the superseding of adapted local species. Genetic resources must be preserved for the constant regeneration of nature in the generations to come. A protection system for inventions must therefore ensure that species diversity is conserved and its sustainable use is not put at risk.

IV Afterword

This paper presents the status of the ECNH's discussion at the end of summer 2001, integrating the suggestions, criticisms, additions and improvements introduced by the public discussion with experts and lay people at the event organised by the ECNH at the University of Fribourg in May 2001. Nevertheless, even these additions cannot in any sense finalise the discussion and assessment of the arguments assembled here.



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