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PATENT LAW POLICY IN BIOTECHNOLOGY*

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Environmental law has developed and is commonly understood to be a brake on a fully speeding market economy. Due to the power of the engine the brake is now red-hot. Maybe, the driver can be persuaded to make more prudent use of the accelerator, or, in non-metaphorical words: the very body of law which instigates economic growth and dangerous side-effects may deserve to be explored as to its potential ecological sensitivity.

Patent law belongs to this category of law. In the area of biotechnology the debate about coping with environmental risks crystallized in a regulatory framework, but left intellectual property law largely untouched. Granting an inventor a limited time for the exclusive exploitation of an invention, however, is not a neutral device for enabling societal interaction but an interventionist instrument of the State designed to foster progress. As such, it has constantly to prove that it still serves its goal, and particularly so when applied to new technologies. Patenting life forms is even more challenging because it puts the very notion of progress into doubt.

It is a long time since patent law was exposed to public debate. During the eighteenth and nineteenth centuries the battle was concerned with whether patents would stimulate progress or, on the contrary, hinder it by monopolizing know-how.[1] But in the 1870s, when most of Europe and North America had adopted patent legislation the further development of patent law became depoliticized. Take, for instance, the German case.

Patenting had previously been discussed as a matter of best economic policy (ie of furthering or impeding industrial progress), but after promulgation of the Patent Act in 1877 a doctrine was developed which provided patent rights with a moral basis and thereby immunized it against political review.[2] In 1878, an outstanding author, Joseph Kohler, began his most influential book on patent law by writing: 'He who creates a new good has the right to make exclusive use of the good in so far as this good is apt to be used exclusively'. Citing John Locke, Kohler argues that the idea of founding property on work must also apply to immaterial goods.[3]

Criticism from two equally outstanding public law scholars, Paul Laband[4] and Otto

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[1] F. Machlup, *Die wirtschaftlichen Grundlagen des Patentrechts*, *GRUR Int* (1961), 373–90 and 524–37.

[2] W. R. Walz, *Der Schutzinhalt des Patentrechts im Recht der Wettbewerbsbeschränkungen*, (1973), 121.

[3] J. Kohler, *Deutsches Patentrecht* (1878), 1, 7.

[4] P. Laband, *Die Literatur über das Deutsche Patentrecht* in *Zeitschrift für das gesamte Handelsrecht 23* (1878), 616–29, at 625.

Mayer,[5] remained unheeded. They argued that patent law should be understood as public, not private law, which in those times meant to regard it as disposable state intervention. Kohler's starting point was, so to speak, pre-societal, a matter of natural order which expresses itself much more in the stable private law than in public law. The conception became authoritative, if only in the somewhat more flexible version that the ground for a patent is investment of labour or money, not labour alone.[6]

In the decades that followed, this foundation of patent law allowed new technologies to be discussed merely as doctrinal problems not as questions of economic policy. New technologies were subsumed under the criteria of patentability and the scope of protection. When these criteria did not fit, they were stretched or reformulated. The related discourse was a predominantly scholarly one; it was kept within the closed circles of attorneys, administrators, judges and academics specializing in intellectual property law.[7]

This is not to say that those circles have completely disregarded the economic consequences of these doctrines. The pro-patent law faction has here and there alluded to the blessings of patent law promoting inventiveness and innovation. This has become even more frequent in recent times when functionalism permeated positivist legal thought and made scholars think about private law in terms of policy variations. But patent lawyers, when stressing the promotional effects of patent law, have tended to take the existence as well as the desirability of those effects for granted. The hypothesis, though questionable both in theory and as a matter of practice, was turned into an axiom which served to justify any coverage of new technologies by patent protection.

This syndrome of argument proved capable of subsuming technologies like metallurgy and chemistry under patent law without major problems.[8] Biotechnology, however, has proved a more intricate matter. We shall see what steps intellectual property law had to take to permeate this technology as well.

1. Breeding Technology

During the thirties and, following a pause during the war, the late forties and fifties, a debate unfolded among intellectual property lawyers about whether breeding of plants could be subsumed under patent law or should be provided with a special protective regime. Incidentally, the debate also clarified the patentability of breeding of microorganisms and animals. Looking back from the present debate about patenting and

[5] O. Mayer, *Die concurrence déloyale* in *Zeitschrift für das gesamte Handelsrecht* 26 (1881), 363–437, at 436.

[6] This resounds Locke's own broadening of the labour theory which allowed to justify property of the entrepreneur in objects produced by paid labour. See J. Locke, *The second treatise of government* (1690), ed 1952, paras 27, 28, and the comment by C. B. Macpherson, *The political theory of possessive individualism* (1962), 214 seq.

[7] Interestingly, this hermetic nature of the discourse persisted even during the Nazi-regime. For instance, almost no allusion to Nazi-ideology was made in the debate of the thirties about patentability of plants.

[8] Chemical substances were originally regarded as phenomena of nature and explicitly excluded from patentability (*Patentgesetz* of 1877, RGBl. I 501, para 1 no 2. Already Kohler criticized this. He suggested that at least chemical compounds were inventions, not discoveries: Kohler (n3), 74. Later on the Act was amended to adopt this position.

genetic engineering one is struck by the similarities of the respective arguments. The main points for[9] and against[10] patenting were:

(1) Against: Patents are reserved to dead matter or processing dead matter. Life cannot be manufactured.
For: Patents protect human ingenuity. Whether this concerns dead or living matter is of secondary significance.

(2) Against: Breeding technology is collective knowledge of the farmers' community and may not be privatized.
For: Individual investment in enhancing this knowledge deserves a protected return.

(3) Against: Patent protection for any new process or seed prejudices farmers as to the quality of what they purchase.
For: Quality is not an issue for patent law. It should be tackled by separate administrative laws, eg pre-market licensing of seeds.

(4) Against: An enabling description of how the organism was bred, which is a prerequisite of a patentable invention, is impossible because breeding a living organism is not repeatable with precisely the same result.
For: A living organism can reproduce itself. Disclosing this capacity to the public is enabling enough. Natural reproducibility may replace artificial constructability.

(5) Against: Assuming that natural reproducibility of a new organism is the enhancement of technology which is presupposed by patent law, disclosure rules would require that the organism is handed out to any interested person.
For: This would force the patent applicant to deliver a veritable production facility. Prosecution for its utilization would be difficult. A description of the process or product must suffice.

(6) Against: Assuming that living organisms were patentable, the licensee would have to be free to use the organism for production, eg of fruits including seeds just as the licensee of a patented machine is free to use the latter for eg sewing textiles. In respect of this free utilization, the patent must be considered exhausted.
For: To reproduce the organism must be taken as violating the patent, because it amounts to either producing the protected object or making use of the latter.[11]

(7) Against: Patent protection would enormously complicate dependent breeding and lead to patent 'pyramids' which reach into new varieties.
For: This is normal in patent law in general and has thus far not led to unsurmountable hurdles.

The pro-group appears to be contradictory in one important respect. On the one

[9] The most important contributors were S.v.d. Trenck, *Zum Patentschutz von Pflanzenzüchtungen* in *GRUR* (1939), 437–47, and H. Schade, *Patentierung von Pflanzenzüchtungen* in *GRUR* (1950), 312–22.

[10] See F. Herzfeld-Wüsthoff, *Zur Erteilung des ersten amerikanischen Patentrechts* in *GRUR* (1932), 24–7, F. Wüsthoff, *Erschließung des Patentrechts für neue Gebiete* in *GRUR* (1952), 230–4, W. Pinzger, *Über die Patentfähigkeit von Pflanzenzüchtungen* in *GRUR* (1938), 733–48, W. Marx, *Zur Patentierung von Pflanzenzüchtungen* in *GRUR* (1952), 456–60.

[11] Marx (n10), 459. In contrast to this broad conception, Pinzger (n10), 739, proposed that farmers be allowed to reproduce seeds for their own use.

hand, they posit a dominant role of human intelligence in order to reject the living-matter argument, but on the other hand, they forget about this when it comes to description, disclosure and exhaustion. Here, natural characteristics all of a sudden are resurrected as a forceful reason for lowering the description requirements, for avoiding delivery as a means of disclosure, and for extending the protected scope to any reproduction of the patented product.

This contradiction and a general feeling that intellectual property could not be available as long as what was to be protected was not yet intellectually well understood, may have influenced the legal outcome of the reported debate. The pro-patent faction lost. Since the early thirties the Reichspatentamt (RPA), probably under the influence of the introduction of the US Plant Patent Act of 1930 and the US Patent Office's patent of 1932 for the breeding of a rose, had abandoned its former negative attitude[12] and was considering granting patents for breeding processes and products,[13] but the Government then intervened. In order to avoid higher food prices arising out of royalties, the Reichsregierung decided to provide plant breeders with much weaker protection. This consisted of a system of licensing the marketing of seeds and granting protection for the trademark of the licensed seed.[14] Within this framework farmers as well as second breeders remained free to utilize the seed.

Subsequently, the breeders subscribed to the weaker system. They withdrew former applications for patents or even returned plant patents.[15] But patent protection was not explicitly excluded by the law. It remained a latent possibility for future use.

After the war, a special regime for plants was created, the so-called 'plant variety protection' (Sortenschutz) or 'breeder's right'. Acts of 1952, 1968 and 1985[16] introduced such a breeder's right for newly invented or discovered plant varieties which belonged to a species listed in an official plant species register, and which was distinct from other varieties, uniform, stable, and new as compared to existing commercial varieties. In contrast to the more formal conditions of the patent (these being novelty as compared to already publicized inventions, non-obviousness of the newly created knowledge, and industrial applicability) the criteria for plant variety protection, especially homogeneity and stability, imply a more qualitative checking by the responsible agency. As to the content of the variety protection, the holder of the right is granted the exclusive use of the plant variety. There are, however, two important exceptions, the farmer's privilege, allowing farmers to reproduce seeds for their own use, and the breeder's privilege, allowing breeders to use seeds for the development of new varieties.[17]

[12] In 1914, the *Reichspatentamt* had refused to patent agricultural and breeding processes on the ground that these techniques were based on living nature. See Schade (n9), 313.

[13] In 1932, the RPA considered to patent a method of harvesting rye plant twice a year. Whereas it generally conceded that influencing the functioning of living organisms could be regarded as a technique, it denied a patent because the method was not new. See Schade (n9), 314; Lindenmaier, *Die Vereinheitlichung des materiellen europäischen Patentrechts* in *GRUR* (1942), 485–516, at 493.

[14] *Verordnung über Saatgut* of 26 March 1934, *Reichsgesetzblatt* 1934 I 248. On the trademark protection see H. Neumeier, *Sortenschutz und/oder Patentschutz für Pflanzenzüchtungen* (1990), 16 seq.

[15] The applications concerned a special tobacco, lupine and pea. See Schade (n9) at 314. A reason for the reticence of the breeders may have been that in Germany breeding was done by small cooperative societies owned by farmers. This guaranteed the dominant influence of the farmers' interest.

[16] *Saatgutgesetz* of 27 June 1952, *Bundesgesetzblatt* 1953 I 450; *Sortenschutzgesetz* of 20 May 1968, *Bundesgesetzblatt* 1968 I 429; *Sortenschutzgesetz* of 11 December 1985, *Bundesgesetzblatt* 1985 I 2170.

[17] Plant variety protection as a private right was supplemented by an administrative pre-market licensing scheme

This protective scheme was also adopted by other European states. It received an international basis through the *Convention Internationale pour la Protection des Obtentions Végétales* of 1961[18] and has since then been vigorously promoted by the organs of the Union (UPOV) set up by the same convention.

Art 2 of the UPOV-Convention further strengthened the plant variety protection scheme by disallowing the combination of patent protection and variety protection. The Member States had to opt for either patent or variety protection, and most chose the latter.

So did Germany. The Patent Act of 1976 excluded varieties of registered species from patentability.[19] As the species register has become quite comprehensive over the years nowadays almost any old and new variety falls into the realm of plant variety protection.[20] Patent law has become residual both in relation to plants themselves, and also to breeding methods because these too, if 'mainly biological',[21] were explicitly excluded from patentability.

Only with the advent of gene technology which allows the borders of species to be crossed and employs non-biological methods has patent law gained new ground. But this will be discussed in the next section. In the present context it suffices to say that the plant variety protection scheme has survived this new challenge, although in a somewhat modified form. International discussions about the 'interface between patent protection and plant breeders' right'[22] have led the parties to UPOV to instill some patent thinking into plant variety protection. The new UPOV-Convention of 19 March 1991, abandons the prohibition of double protection thus allowing the Member States to provide patentability in addition to variety protection (Art 2).[23] The breeder's right is extended to varieties 'essentially derived from the protected variety' (Art 14 para 5) which means that the notion of dependency, a device charactertistic for patent law, has entered variety protection. This clause precludes what is a frequent subversion of the breeder's right, the creation of varieties which are only slightly distinct from the initial variety. Another, approximation to patent law is that whereas the breeder's privilege is retained as obligatory, the farmer's privilege is made optional. This means that the Member States are allowed to abandon it. The farmer's associations which had strongly advocated an obligatory farmer's privilege[24] could not carry their point through.

Leaving this trajectory on plant breeding we now turn back to the breeding of microorganisms and animals. In contrast to plants for which a separate scheme of a

which aims at ensuring high quality of seeds. The conditions for granting a licence are the same as those for the breeder's right plus a further, even more 'qualitative' requirement, the agricultural value ('landeskultureller Wert'). The scheme originates from 1934 (see n14) and entered into the *Saatgutgesetz* of 1953, sec 41, which was succeeded by the *Saatgutverkehrsgesetz* of 20 May 1968 (*Bundesgesetzblatt* 1968 I 444) sec 30.

[18] 815 UNTS 89.

[19] *Patentgesetz* of 21 June 1976, para 1a, equalling para 2 no 2 *Patentgesetz* of 16 December 1980 (*Bundesgesetzblatt* 1981 I p1).

[20] F. Wüsthoff, H. Leßmann, D. Wendt, *Sortenschutzgesetz, Kommentar*, 2nd ed 1990, 39

[21] See n19.

[22] See *Committee of Experts on the Interface* ..., report of the meeting at Geneva, 29 Jan–2 Feb 1990, WIPO/UPOV/CE/I/4. The report can be obtained from WIPO or UPOV.

[23] The new version is reprinted in *GRUR Int* (1991), 538. The EC Commission *Proposal for a Council Regulation on the Community Plant Variety Protection* of 6 Sept 1990, OJ C 244 1, which in Art 1 prohibits double protection, will have to be discussed anew under this perspective. Given the powerful position of the farmers in the EC the prohibition will probably be maintained.

[24] See report (n22) para 47.

breeder's right was introduced no specific variety protection legislation was devised in this context, either in Germany or elsewhere. Instead, the courts stepped in and gradually developed the patent line further. In 1969, the Bundesgerichtshof (BGH) recognized the patentability of animal breeding methods provided the description of the breeding was 'enabling', ie allowed a repetition that would produce the same result.[25] In practice, this could rarely be shown. Therefore, it was no great loss to animal breeders when the amendment of 1976 to the Patent Act, reflecting Art 53 lit b of the European Patent Convention (EPC) of 1973, expressly excluded biological methods of breeding animals from patentability.[26] The amendment also excluded the patenting of animal varieties as such, but this only corresponded to the already long-lasting practice.

As to micro-organisms, it has been the practice of the patent offices since 1922[27] to grant patents for processes of breeding or using such organisms. In 1975, the BGH extended the patentability to micro-organisms themselves but required, just as in the decision of 1969, an enabling description of how they were bred.[28] Only in 1987 the court, yielding to international practice which had been established in the meantime, abandoned this requirement and acknowledged the deposit of the micro-organism as a sufficient description.[29] But this move was already heavily influenced by the new gene technology; the impact of this technology on intellectual property law became so intense that it deserves separate analysis.

2. Gene Technology

Gene engineering allows nature to be cut into parts and recombined by transferring some parts across the boundaries of species and even genera. In contrast, classical breeding remains within those boundaries and may produce varieties of the species but—except for non-reproducing hybrid forms—not new species as such. This cross-cutting capacity of genetic engineering has challenged the variety protection system and has once more incited the patenting debate.

The new technology is capable of isolating and transferring genes, proteins and cells thereby altering the properties of plants and plant material. It was debated whether logically only the new plant should be protectable under the plant variety protection system, or whether the gene, protein or cell itself should be protectable under the patent system. For instance, a claim may be formulated to include 'various plants which carry a gene coding for human interferon'.[30] The various plants bearing this gene may belong to totally different species. They do not constitute a variety in themselves because they differ in too many respects.[31] Therefore, plant variety protection was not available. The

[25] Decision of 27 March 1969 ('Rote Taube') *BGHZ* 52, 74 (83).

[26] See above n19. As already mentioned, the exception also covers plants.

[27] In 1922, the RPA had granted a patent for a process of exploiting a vaccine from a tuberculosis bacillus, see Schade (n9), 314.

[28] Decision of 11 March 1975 (Bäckerhefe) *BGHZ* 64, 101 (107).

[29] Decision of 12 Feb 1987 (Tollwutvirus), *BGHZ* 100, 67.

[30] Cf R. Moufang, *Genetische Erfindungen im gewerblichen Rechtsschutz* (1988), 190.

[31] Compare the definition of a variety in the *International Code of Nomenclature of Cultivated Plants*, cited in Moufang (n30), 189, n13: 'Assemblage of cultivated plants which is clearly distinguishable by any characters (morphological, physiological, cytological, chemical or others), and which, when reproduced (sexually or asexually), retains its distinguishing characters'.

question arose: should the claim, or more precisely, the gene as far as it modifies various plants remain unprotected or be patentable? The same question arose as to genetic engineering as a means of producing new varieties, eg fusion of cells of different varieties which leads to a hybrid new variety.

Patentability was also to be clarified as it related to processes and products outside the realm of possible plant variety protection, namely with regard to genetic modification of micro-organisms, animals and even human beings.

The topics debated in this respect more or less resembled those raised during the former debate about more traditional breeding:

– The general 'living-matter' argument had already been rejected by the BGH in his Rote Taube decision of 1969. The court mentioned the Watson and Crick discovery of the gene structure and inferred that life obeyed regularities which were calculable and open for manipulation.[32] About the same was said by the US Supreme Court in the Chacrabarty case of 1981.[33]
– The 'phenomenon-of-nature' argument holds that objects like genes, proteins or cells including their reproductive capacity are natural phenomena and can therefore, in terms of the European patent laws, be discovered but not invented. They are said to belong to everybody, not to the individual researcher.[34] The counter-argument which has been adopted by practice in Germany states that natural phenomena which either can be artificially produced[35] or have been selected or isolated with some sophistication[36] should be regarded as technical products.
– A related argument not reflected in the area of classical breeding points at the similarity of genetic information with plans, rules or processes for mental activities which are exempted from patenting under Art 52 EPC and sec 1(2) Patentgesetz. The usual counter-argument is: Genetic information is tied to matter and addresses the cell, not the human intellect. Furthermore, if genetic information, as it is said, resembles a computer program which is also not patentable, this does not speak against patentability of genetic information, because it would be preferable to make computer programs patentable.[37]
– The 'enabling-description' argument denies that a product of genetic engineering can precisely be described. The response: natural reproduction of the product should be recognized as an adequate substitute. For proving this, the deposit of the gene or cell shall be sufficient. Besides, progress in genom analysis may increase the possibilities of precise description.
– The 'disclosure' argument infers from the above response that anybody must have access to the deposited invention and may obtain a sample. The patent faction in turn points at the risk that unauthorized persons may reproduce the sample. Hence,

[32] Op Cit (n25) 78 seq.
[33] Decision of 16 June 1980, 100 S.C. 2204 = *GRUR Int* (1980), 627.
[34] 333 US 127, Decision of 16 Feb 1948 (*Funk Brothers Seed Co v Kalo Inoculant Co*), at 130.
[35] *Bundespatentgericht*, Decision of 28 July 1977 (Naturstoffe), *GRUR* (1978), 238.
[36] *Bundespatentgericht* (BPatG), Decision of 5 April 1976 (*Lactobacillus bavaricus*), *GRUR* (1978), 586; the American *Court of Customs and Patent Appeals* (CCPA) overruled the *Funk Brothers Seed* decision of the Supreme Court (see n34 above), in its decision of 6 Oct 1977, 563 F 2d 1031 – in *re Bergy*.
[37] Moufang (n30), 180. On first steps towards patentability of mathematical algorithms see H. T. Markey, *Patentierbarkeit mathematischer Algorithmen in den Vereinigten Staaten* in *GRUR Int* (1991), 473–5. Computer program protection is being developed in the framework of copyright law rather than of patent law. See EC Directive of 14 May 1991, OJ L 122, 42.

Rule 28 of the EPC gives the patent applicant the right to opt for a scheme according to which during the period of pending patent application only approved experts may be given a probe. Once the patent is granted, only non-reproducible material may be handed out, for instance not the hybridoma cell which produces antibodies but only the antibodies themselves. Otherwise, the patentee would give a veritable production facility away.[38]

— The 'exhaustion' argument says that assuming patentability is accepted patent protection must end when the patented product, eg a bacterium, has been sold with the consent of the patent holder and the acquirer uses it, even for natural reproduction. Only an artificial reconstruction of the bacterium would violate the patent right (as it is, when someone reconstructs a patented machine). Not surprisingly, the patent faction disagrees saying that this would miss the very essence of the patent which is to dispose of the replicative capacity of the bacterium.

— The 'dependency' argument finds that patentability of genetically engineered organisms will lead to pyramids of dependent inventions and thus complicate further research and development.[39] The patent law faction responds that this is normal in patent law and has in other fields not caused unbearable complications.[40]

As in the earlier debate of the thirties there is a contradiction in the position of the pro-patent faction which resembles the older faction. On the one hand, human intelligence is stressed in order to rebut the living matter and phenomenon of nature arguments, but when it comes to description, disclosure and exhaustion ample reference is made to the natural characteristics of the patented object.

Nevertheless, this time the patent side has more or less won the battle. Only a more and more restricted field remains unscarred, ie plant and animal varieties in themselves and mainly biological methods of their production.[41] Genetically engineered genes, proteins and cells of plants may be patented if their properties reach beyond one variety. It has become merely a question of skilfully formulating the claim if one wants patenting instead of plant variety protection.[42] Those States, which in correspondence with the 1991 UPOV Convention opt for double protection, will issue patents for genes, proteins and cells even if these express properties peculiar to just one variety, in addition to patents for the variety itself. This means that the breeder's and farmer's exception to the breeder's right will have to yield to the patent. Furthermore, there is a policy to restrict the field of applicability of plant variety protection. For instance, hybrid progeny of parents belonging to two varieties has recently been exempted from plant variety protection on the ground that such hybrid products do not meet the stability criterion required for plant variety protection.[43]

Whereas Art 53 (b) EPC excludes patents for animal varieties it is accepted practice to patent genetically engineered animal genes, proteins or cells. In addition, we are

[38] K. Dänner, *Bedürfnisse der Anmelder biotechnologischer Erfindungen* in *GRUR* (1987), 315 seq, at 316, J. A. Goldstein, *Der Schutz biotechnologischer Erfindungen in den Vereinigten Staaten* in *GRUR* (1987), 310–17, at 312.

[39] For plant breeding see R. Lukes, *Das Verhältnis von Sortenschutz und Patenschutz bei biotechnologischen Erfindungen* in *GRUR Int* (1987), 318–29.

[40] Neumeier (n14), 243.

[41] Art 53 (b) EPC.

[42] R. S. Crespi, *Biotechnology and intellectual property* in *Trends in Biotechnology* (1991), 151 seq, at 155.

[43] *European Patent Office* (EPO), decision of 10 Nov 1988 (*Lubrizol*) in *GRUR Int* (1990), 629. The paradoxical consequence is that new types of plant material are patentable, but not the finished variety: Crespi (n42), 155; E. S. v.d. Graaf, *Anmerkung* in *GRUR Int* (1990), 632–4.

facing the patenting of an animal itself: the EPO recently decided to grant a patent for the US patented Harvard onco mouse. The agency did not regard the patent claim which related to a 'transgenetic non-human mammal' to concern an animal variety.[44] Therefore, Art 53 (b) EPC did not apply. Ethical objections were rejected on the ground that, because it helped improve the testing of anti-cancer drugs, the onco mouse served the public good.

Plant or animal varieties may even themselves be subsumed under a patent if the variety is produced by nonbiological methods and the application requests a product by process patent. Again, the US pioneered in this respect.[45] An EC Commission proposal of 20 October 1988 for a directive on patent protection for biotechnological inventions follows this line.[46]

In addition, the Art 53 (b) EPC exemption for biological methods of producing new plant or animal varieties is more and more narrowly interpreted in order to extend the patentable space for genetic engineering. According to the proposal for an EC directive on patent protection, a method is already to be regarded as non-biological (and hence patentable) when, in step-by-step methods, only one step is based on genetic engineering.[47]

As to the scope of a patent right the proposed EC Directive decides a number of open questions by taking the position of the pro-patent faction. Art 11 makes clear that a patent for reproducible matter also covers the material obtained from reproduction, and further applies when the product was sold on the market with the patent holder's consent. In addition, Art 12 extends this narrow concept of exhaustion to product by process patents.[48]

3. Explanation

Understanding this near-perfect victory of patent law may be easier if the interests and strategies which made the victory possible are analysed.

Whereas the nineteenth-century patent legislation was quite openly an outcome of political struggles between free trade promoters and protectionists, the interests behind the two steps towards patenting of biotechnology are less easily identifiable because the related debates remained in the inner circles of intellectual property lawyers. Doctrinal debates, in contrast to political debates, tend to disguise the underlying motives. They complicate the matter once more by adding professional interests (of the patent attorneys, the patent judges, etc) to the more basic substantial interests.

As to the debate about the traditional breeding of plants which randomly also

[44] *EPO Technical Appeal Chamber*, decision of 3 Oct 1990 in *GRUR* (1990), 978. The argument is very positivistic because by Art 53 (b) EPC it was meant to exclude patenting of living beings (be they varieties or genera or whatever). On the other hand, at the times of EPC one could not foresee how much biotechnology would become able to cut life into pieces and recombine them. For a more comprehensive discussion of animal patents see W. H. Lesser (ed.), *Animal Patents* (1989).

[45] *Ex parte Hibberd*, 227 *USPQ* 473 (*PTO Bd. Pat. App. & Int.*, 1985).

[46] OJ C 10, 1989 3, Art 12 (2).

[47] See proposal (n46) Art 7.

[48] *The European Parliament Commission for Law and Human Rights* favours a broader concept of exhaustion. See W. Rothley, *Draft of a Commission Report* of 4 June 1991, Arts 11 and 12. The Report interestingly proposes also to introduce a farmer's privilege into the patent law (see Art12a).

concerned micro-organisms and animals, it seems that the promotional impetus towards patenting was indeed mainly based on the professional interests of the patent lawyers. The breeders who could be expected to nourish the flame were content with the minor protection provided by plant variety legislation. This seems to be due to the fact that in Germany commercial breeding has traditionally been practised by small co-operative societies of farmers. Therefore, the breeders could not form an interest independent from or even opposed to the farmers' interest. The farmers themselves, making themselves heard through the *Reichsnährstand* during the Nazi regime,[49] wanted to be free to use seeds for their own further breeding.

In contrast, the debate about patenting gene technology had in its background a much clearer-cut and more straightforward interest, namely that of the chemical industry. This industry has invaded the research and development of genetic engineering, including the plant breeding sector where it swallowed one small co-operative after the other and taught them the new technology. The chemical industry acts on the world market and experiences the need for patent protection from this orientation. As one industry patent lawyer sees the 'needs of the patent applicants for biotechnological inventions': patent law shall provide the inventor with the best protection, be pragmatic and flexible instead of over-positivistic in order to reach this end, minimize formalities and fees, and be internationally harmonized.[50]

The lawyers related to state agencies and courts could be expected to take a more independent position which stresses the anti-competitive effects of too broad a patent protection. In former times, the trade liberalists did take this position,[51] and it is still reflected, for example, in the reluctance of the BGH to accept an enabling description by way of deposit of the organism. On the other hand, in a world of international competition, the States have to defend their national industry. One way to do this is to maximize patent protection. The US in particular has been eager to discuss and develop patent law under this perspective.[52] But also the German courts had finally to yield to international standards, pushed by international developments like the EPC, the Budapest Convention on deposit rule and the EC proposals for a patent directive and a plant variety protection regulation, developments which had to a considerable extent been prompted by the interested industry and their professional and academic mouthpieces.[53]

Stronger opposition to the victorious march of patent law in gene technology lagged behind. Citizen groups, churches, concerned scientists, the Green Party, etc have, since the beginning of the gene debate, directed their efforts towards abating risks to health

[49] Compare Pinzger (n10) at 743 seq.

[50] Dänner (n38), 315.

[51] Compare Machlup (n1).

[52] The Office of Technology Assessment of the US Congress has published three widely distributed reports which take the patent issue up. The predominant perspective is whether the law sufficiently strengthens the competitive position of the US on the international market. For a conclusion see *Commercial Biotechnology* (1984), 403: 'The U.S. intellectual property law system appears to offer the best protection for biotechnology of any system in the world'. See also *Impacts of Applied Genetics* (1981), 237 seq, and *New Developments in Biotechnology, Vol. 5, Patenting Life*, ed by US Congress, Office of Technology Assessment (1989).

[53] Very forceful players in the game were the Max-Planck-Institut für Ausländisches und Internationales Patentrecht, Munich, and the International Association for the Protection of Industrial Property (AIPPI). For details about their strategies see Marie-Angèle Hermitte, *La protection de l'innovation en matière de biotechnologie appliquée à l'agriculture* in *Office Parlementaire d'Evaluation des Choix Scientifiques et Technologiques, Rapport sur les applications des biotechnologies à l'agriculture et à l'industrie agroalimentaire* (1990) Vol II, 115–290, at 284.

and the environment by regulatory action. Only recently has a 'critical mass' taken up the patent issue. However, they have primarily tackled the most symbolic point at issue, the patenting of animal species, without fully realizing how much of animals and the other living world has already become patentable. Also, they have hardly attempted to transform their opposition into arguments of legal doctrine, which is the password for being heard in the inner circles of the legal debate.[54]

4. Evaluation

From the factual observation that the patent law victory in biotechnology was due to the interest and strategies of the related industry and its governmental support, it does not follow per se that the result is justified or that it is not. I shall now turn to this normative question. In answering it, I shall introduce a number of normative criteria that have been postulated, apply them to biotechnology and, if they are applicable, consider whether they are reasonable. If one surveys the various criteria for evaluating whether biotechnology ought to be patentable, substantialist and functionalist (or, in Max Weber's terms, *wertrationale und zweckrationale*) principles may be distinguished. They are tied to the more general principles of justifying patent law, but adopt specific traits when applied to biotechnology.

a) Substantialist Theories

The most common principle rests on the labour theory of property. It says that he or she who has taken pains to make an invention deserves time for exclusive exploitation.[55] The exclusive right is given as a compensation for the intellectual labour involved.[56]

The labour theory of patent law encounters difficulties where the invention is in truth a discovery. Gene technology is a case in point. Most of its 'inventions' are

[54] One first instance is an opposition filed by Greenpeace UK to EPO against a patent for herbicide-resistant plant cells. The intervener argues that the possible environmental effects (creation of new pests, spread of resistance to weeds, reduction of biological diversity, increase of herbicide use) violate the principle of Public Order (Art 53 (a) EPC), that the process of modifying the cell is an 'essentially biological process' in the sense of Art 53 (b) EPC, and that the modified cell is not an artefact as required by the term 'invention' in Art 52 EPC. See *Notice of Opposition* against European Patent No 0242236.

[55] See above n3.

[56] Some German authors go even so far as to claim that the legislative bodies are constitutionally obliged to provide this exclusive right (V. Vossius, *Bedingungen für die Freigabe von Mikroorganismus-Kulturen* in *GRUR* (1977), 74–83, at 81; F.-W. Engel, *Sachschutz für Mikroorganismen nach dem neuen deutschen Patentrecht* in *GRUR* (1987), 332–8, at 338; H. G. Hesse, *Der Schutz der züchterischen Leistung und die Grundrechte* in *GRUR* (1971), 101–6 at 104). This is, however, a misinterpretation of a decision of the *Bundesverfassungsgericht* (BVerfG, decision of 15 Jan 1974, BVerfGE 36, 281). The court had to decide whether the right to be granted a patent, which is provided to the inventor of a patentable invention, is constitutionally protected against legislative modification. In casu, the modification consisted in liberalizing disclosure rules. The court held that parliament has latitude for this kind of modification. It did not say anything about a constitutional obligation of the legislator to provide patent rights for inventions which have as yet not been patentable. From the general concept of constitutional protection of property that the court has developed elsewhere, one can infer that the legislator is free to determine if and what kind of genetic engineering should be made patentable, as long as he does not abandon patent law in toto (decision of 15 July 1981, BVerfGE 58, 330, 338 seq). This does not hinder the legislator making his decision on the basis of a substantialist principle. If we assess this principle we are therefore discussing at a level of political philosophy, not of constitutional doctrine.

discoveries of natural phenomena, as are genes, plasmids, proteins, cells, reproductive capacity etc. Although promoters of this theory hasten to point to the sophisticated and costly labour involved in the research, and also at the increasing ability of artificial construction, the share of nature compared to that of skill remains considerable.

Nevertheless, when it comes to defining the patent claim, natural phenomena, such as the programme of the inserted gene or the reproductive capacity of the micro-organism, cannot be separated from the artificial part of the package and must be included into the claim. But this contradicts the labour theory of patents because something is given to the inventor which had not been created by him or her.

Therefore, the labour theory is not well-suited to justify the patenting of biotechnology.

Another substantialist theory attacks such patenting. Building upon the phenomena of nature argument it does not, like the labour theory, point at nature's 'givenness' in contrast to human inventions, but at nature's integrity and dignity in contrast to human failing and pretension. For some, there is a religious foundation to this, as it is expressed in the statement of a number of American churches regarding the decision of the US Patent Office to patent the onco mouse:[57]

> This decision is a matter of deep philosophical and spiritual concern. It portends fundamental changes in the public's perception of, and attitude towards animals, which would be regarded as human creations, inventions, and commodities, rather than as God's creation and subjects of nature.

This reflection can also be framed in more secular terms. One would then stress the long evolutionary learning built into genetic information and deny that humanity is intelligent enough to replace this knowledge by its own. Language reveals this pretension by calling the crossing of different species hybridization, which derives from the Greek word hybris and means transcending the right measure.[58]

This hybris theory if rigorously applied would exclude any patenting of living nature. Nobody seems to go so far as to postulate this, but then difficulties arise as to how to draw lines between patentable and non-patentable nature. If one refuses to patent hybrid forms, why not any manipulation of the genom? If any manipulation of the genom, why not also traditional breeding techniques? What is natural, what artificial? Are not at least some artifacts acceptable because they bear high benefits? It seems that the scope of evaluative criteria is insufficient. In addition, the public order clause in Art 53 (a) EPC, which would be the natural legal reference point for substantialist objections, is too narrow a principle to deal with the fundamental economic power released by patent law.

b) Functionalist Theories

Functionalist theories start from the more or less explicit assumption that patent rights are something which it is for society to provide and which society will only provide for a quid pro quo. More substantial reasoning would add that the invention is in fact the result of societal efforts (education, tradition, etc) and is collective rather than

[57] Reprinted in: *New Developments in Biotechnology* (n52), 134.
[58] See W. Pape, *Griechisch-Deutsches Handwörterbuch* (1849): 'Das Hinausgehen über das rechte Maß'.

individual knowlege. The privatization of parts of this collective knowledge is the quo for which there must be a quid. Of what this consists can be identified if one looks at the functions of patent law.

(i) Scientific and technical progress—in the abstract

The function most commonly cited is scientific and technical progress. Progress is regarded as deserving of society's effort, including enabling legislation like patent law. In a recent publication[59] one can read:

> Our argument rests on a simple assumption: when it comes to invention and innovation, faster is better.

Although a relationship between patent law and scientific and technical progress is not easy to prove empirically, the evidence for a positive correlation and mutual reinforcement appears to be sufficient.

One simple piece of evidence is that industry would not have constantly pushed for patent legislation had they not experienced its positive impact and growth. States without a developed patent law tend also to be industrially less developed. The often repeated statement of industrial representatives that without patent law investment into research and development would decline may be taken as further proof. The alternative to patent protection, namely keeping the invention secret, may function in some cases like that of the 100-year-old Coca Cola recipe, but is not regarded to be reliable in general.[60]

Empirical studies show a more diverse picture. For instance, one study concluded that in the pharmaceutical industry R and D investment would have been reduced by 64 per cent without patent protection, as opposed to a mere 5 per cent in the electrical industry.[61] This may be due to the fact that the development of a patentable drug is more costly than that of a patentable electrical device. The value of patent protection seems to rise with the costs of the invention. From this it follows that genetic engineering which is also a very costly technology will proceed faster with rather than without patent protection.

This promotional effect can be expected to arise from the monopoly side of the patent, but such an effect may also result from the patent's implied mechanism to reveal information. Often the disclosure requirement is seen as promoting growth. It is doubtful if this holds true. A re-examination of five empirical studies has shown, that patent disclosure was the last of ten external innovation impulses investigated. Only for 10 per cent of the interviewees did patent disclosure play a role at all. The author shows instead that patented information spreads and incites more often via licence policies. The patentee feels rewarded and continues with R and D, the licensed person searches for circumventive or contrasting innovation.[62]

[59] R. P. Merges, R. R. Nelson, '*On the complex economics of patent scope*' in *Col Law Rev* 1990, 839–81, at 878.

[60] *Impacts of Applied Genetics* (1981), ed by US Congress, Office of Technology Assessment, 237.

[61] Taylor and Silberman, cited in A. Hilken, *Innovation und Patentschutz auf dem EG-Arzneimittelmarkt* (1989), 114. A more general promotional impact of patent law was also found in a study about 1000 inventions in the oil, pulp, railway, and agricultural industries. J. Schmookler, *Inventions and Economic Growth* (1966), 206 (cited in Hilken (1989), above), 91).

[62] K. H. Oppenländer, '*Die wirtschaftspolitische Bedeutung des Patentwesens aus der Sicht de empirischen Wirtschaftsforschung*' in idem (ed.) '*Patentwesen, technischer Forteschritt und Wettbewerb* (1984), 18, 24

(ii) Scientific and technical progress—in the concrete

The patent law community has as yet shown not the least doubt as to the desirability of scientific and technological progress. Nevertheless, questions must be asked as to the benefits of this progress. The answer, it is true, is easy and in fact tautological if one identifies benefit with competitiveness[63] and the latter with the number of dollars spent or earned. Then the more is the better because the better is the more. Benefit must be defined in more substantial terms.

Along with a seminal book by J. K. Kloppenburg,[64] the notion of 'commodification' may provide the basis for analysis.

Patent law has helped to make biotechnological inventions a commodity. It creates exclusive ownership in a piece of information which originally was collective in two respects: socially, because its origin is societal knowledge, and naturally, because its content is knowledge about nature and nature is, if anybody's, society's property. The exclusive ownership allows the owner to use or sell the commodity.

Commodification implies also that this use or sale is unrestricted. The more that such commodities are produced and the more they are used or sold for producing other commodities, the more profit accrues to the owner. Given the insatiable hunger of the latter there will be a powerful incentive for scientific and technological progress.

However, there is a number of problems associated with the notion of commodification.

(1) Sensitivity of high-yield organisms: Higher yield is an ever-present goal of the patent law discourse, be the yield one of plants, animals or micro-organism. There is, however, a mechanism built into this orientation which could be called the 'dialectics of the more'. High-yield varieties are in general less resistant to diseases and other stress factors. The risk increases when such varieties are employed on the basis of high-yield agricultural methods which seeking economies of scale prefer monocultures.

(2) The realistic potential for and reality of reducing the use of chemicals: More thoughtful supporters of biotechnology put forward its 'biorational' potential. For instance, chemical fertilizers and pesticides could be replaced by crops genetically tuned both to unfavourable soil and climate conditions and to pest resistance. However, in practice the trend points the other way. 'With the seed industry rapidly coming under the ownership of companies with substantial agrochemical interests, seeds and chemicals have come to be linked in proprietary packages'.[65] High-yield crops need even more fertilizers, and it is pesticide, not pest resistance, that is currently promoted.[66]

(3) Invention for demand rather than need: Whether the demand-pull or technology-push hypothesis of innovation[67] is correct or not, in any case inventions and innovations will tend to develop where a demand exists or can be created. This can also be seen in the field of biotechnology. Genetic engineering in drugs R and D is directed

[63] This is the starting point of the *OTA* report *Commercial Biotechnology—An International Analysis* ed by US Congress, Office of Technology Assessment (1984).

[64] J. K. Kloppenburg, *First the seed* (1988).

[65] Kloppenburg (n64), 246.

[66] Out of sixty-four permits, the US Department of Agriculture had issued for deliberate release of modified plants by April 1990, forty concerned herbicide or pesticide resistance and twenty-four non pest- or herb-resistance (author's research).

[67] See Schmookler (n61) and D. Schwartzman, *Innovation in the Pharmaceutical Industry* (1976) respectively, and the discussion by Hilken (n61), 91–4.

more to the greater northern markets than to those of the third world.[68] Diseases typical for affluent societies like diabetes, heart diseases, and cancer are of primary concern, vaccine development for malaria lags behind. A similar situation exists for breeding plant and animal genotypes with poor markets that are adapted to marginal areas or are suited for extensive rather than intensive agriculture.[69]

(4) Curing symptoms rather than causes: Biotechnology as a commodity does not reach the deeper structures of social problems. It grasps and exploits such problems where they appear as demand, not where they originate. By pretending to be able to cure the problems it diverts energy and money from more basic solutions. Medicine provides an example:

> Historically, major changes in the burden of disease have come not from medical innovations, but from environmental improvements. Important drug and vaccine innovations obviously play a role. But an increase in disposable income, purity of air and water, the kinds of food available, the standard of housing and conditions of work are more important overall. Thus, eg products like human insulin made in bacteria may represent a marginal improvement in the assistance available to some diabetics. But the aggregate problem that insulin-dependent diabetes presents to the health service is unlikely to change significantly as a result; firstly, because such affected person still needs treatment, and, secondly, because the numbers of people needing insulin continues to rise.[70]

(5) Expropriation of autochthon production: Patents for processes and products of genetic engineering reduce the space for autochthon farming, because they prohibit farmers from reproducing the seed. In addition, aggressive seed companies, assisted by 'green revolution' subsidy programmes, press farmers in developed and developing countries to abandon indigenous varieties. They sell seeds to them which in many cases were developed from these very varieties.[71] Kloppenburg calls this a new form of primitive accumulation because, as in former times when farmers' interests were expropriated by enclosures, agricultural producers (this time especially in the Third World) lose their independence to develop their own means of production.[72] At the same time this process extinguishes the rich germplasm on which the developed varieties are built.

(6) Subsuming public research under market imperatives: Universities and other public research bodies are increasingly subsumed under the market imperative in the sector of biotechnology. They are in danger of losing the specific function tied to their original detachment from market forces, ie to focus on basic research, to develop products and processes which are less easily marketable but nevertheless needed, to investigate negative effects, and to exchange their information and material freely. Once the motivation of researchers turns from recognition and esteem[73] to money, a development in which patentability of research results plays a major role, these classic functions make way for the more immediate development of marketable goods and for a climate where

[68] J. Elkington, '*Double Dividends? US Biotechnology and Third World Development*' in *World Resources Institute Paper* No 2/1986.

[69] K. Hahlbrock, H. Saedler, F. Salamini, J. Schell, P. Starlinger, *Agriculture, Plant Breeding and Research in Molecular Biology—a European Perspective* (1989), 26, (unpublished paper under EEC Contract No BAP–0534/D).

[70] E. Yoxen, *The Social Impact of Biotechnology* in *Trends in Biotechnology* (1986) 86, 87.

[71] Kloppenburg (n64), 152–90.

[72] Kloppenburg (n64), 281.

[73] Cf P. K. Merton, '*The Normative Structure of Science*' in *The Sociology of Science* (1973), 267–79, at 273: 'The scientist's claim to "his" intellectual "property" is confined to that of recognition and esteem'.

free exchange of ideas and germplasm is made subject to patenting requirements.[74] An empirical study has revealed that 44 per cent of the interviewed scientists with industrial support were persuaded that the university-industry collaborations undermine intellectual co-operation and exchange.[75]

(7) Environmental and health effects: Rapid technological development raises the possibility of overlooking risks for human health and the environment. This is all the more likely when the commodity form allows one to externalize the resulting costs. Patented inventions need most often to be further developed before they lead to marketable products. When such products cause harm and—what is often difficult in biotechnology—causation can be proven, it is the last producer and not the patentee who has to pay compensation.

5. Reconsidering Patent Law

We have seen that patent law provides the legal framework for the commodification of biotechnology and that commodification, though fostering scientific and technical progress in the abstract, leads to serious disadvantages in the concrete. Should patent law in this field therefore be changed or even abandoned?

I should like to repeat that this question is asked from a functionalist perspective; that is to say, structures are assessed and modified with regard to their consequences. They are not questioned from the substantialist point of view of the hybris theory which would forbid patenting because of the appropriation of life by man. (One might say, though, that the disadvantages shown in the functionalist perspective prove that there is hybris indeed).

When patent law was criticized for its negative consequences, two arguments have often been raised in its defence. It is said, firstly, that negative consequences should be tackled by special regulatory law, and secondly, that when patent law is removed other, and less beneficial, means will be found to replace it.

The first argument points to the difference between the patented invention and its application. Applications could be so diverse—detrimental or beneficial—that one would be shooting with a shotgun to hit the patent rather than specific applications. It is indeed a common feature of modern societies to foster two bodies of the law, one for promoting 'industry' and one for limiting it.[76] A representative statement reflects this:

> The ambivalent nature of genetic engineering sets the legal order a double task: On the one side, there ought to be norms which guarantee that the potential of the new technology is most effectively exploited. On the other side, effective regulation must minimize the possible dangers and disadvantages.[77]

[74] In the European patent system, prepublication of an invention destroys its novelty in terms of patent law. But also in the US, where the law provides a one-year reserve time, companies often prefer to keep the information secret. See Kloppenburg (n64), 233 seq, L. Roberts, '*The Race for the Cystic Fibrosis Gene*' in *Science* 240 (1988), 141–4, at 143.

[75] D. Blumenthal, M. Gluck, K. S. Louis, M. A. Stoto, D. Wiese, '*University-Industry and Research Relationships in Biotechnology: Implications for the University*' in *Science* 232 (1986), 1361–66, at 1364. See also V. Weil, '*Policy Incentives and Constraints on Scientific and Technical Information*' in *Science, Technology and Human Values* 13 (1988), 17–44

[76] G. Winter, '*Perspectives for Environmental Law*', in *Journal of Environmental Law* vol 1 no 1 (1989), 38–47.

[77] Moufang (n30), 17 seq.

The author finds the separation of law and their functions 'understandable and legitimate'. But I believe it is questionable. First of all, though it is indeed true that some negative consequences are not directly tied to the application of the patent, as, eg environmental risks, others are. For instance, the impacts on autochthon farming and on public research are directly related to patent rights themselves.

More importantly, as far as consequences are to be tackled by special regulation, the notorious implementation gap has to be taken into consideration. It is not sufficient to point to possibilities of improving implementation. The reason for non-enforcement may be more deeply rooted. It may be that the technological development is so fast and energetic that any regulatory framework is incapable of managing the workload. Take the hundred thousand chemical substances and millions of mixtures which are to be controlled, and add the manifold activities of genetic engineering which bring about more (and even less understood) health and environment risks.

As a result, one should also look at the promotional body of law for remedial changes. It could help reduce the workload for regulatory control if this law were rearranged so as to reduce the speed and energy of new technological developments and thereby give regulation time to do its work. Patent law, which is a major facet of the promotional body of the law, will also have to be considered. Those who cry heresy when hearing this may recall that patent law is a supportive tool. Not providing patentability is therefore equivalent to not providing positive support for an activity. It is not prohibiting this activity. One may also recall that many intellectual phenomena are not patentable or otherwise protectable. For instance, socio-technology like Macchiavelism, Reaganomics, etc have abounded without patent protection.

The second argument mentioned above declares that functional equivalents to patent law would be tried in those areas which were exempt from patent law. One alternative is trade secrets. It is said that relying on trade secrets makes things even worse because in contrast to trade secrets, patent law at least provides disclosure of the patented invention. But this disclosure, if looked at more precisely, does not hold what it seems to promise. I have mentioned earlier that an enabling description can hardly be given in biotechnology. Disclosure of the enabling 'description' would require handing out the organism concerned. This is not required in the case of plants and animals (where even deposit is not required). It is only required in the case of microorganisms but there is pressure to avoid this, too. Patent applicants also try to deposit low quality organisms which are difficult to reproduce. Last but not least: if patent law were abandoned in the public research sector, trade secrets would probably not be used as an alternative, because publication for recognition and esteem could resume its original place. In the private sector trade secrets would indeed be more widely used as a tool, but as the secret vanishes with any disclosure to the public the tool is comparatively ineffective. Besides, when discussing trade secrets as an unpleasant alternative to patent protection, one ought to be aware of the fact that trade secret protection is similarly a benefit granted by the law and therefore open to functionally sound reorganization.[78]

[78] See E. C. Hettinger, '*Justifying Intellectual Property*' in *18 Philosophy and Public Affairs* (1989), 31–52, at 51 seq. Hettinger's functionalist position was criticized by L. Sharp Paine '*Trade Secrets and the Justification of Intellectual Property: A Comment on Hettinger*' in *20 Philosophy and Public Affairs* (1991), 247–63, who advocates a pure Robinsonian 'right to control the initial disclosure of one's ideas' which then has to be purchased by society.

Another alternative which could occupy areas made exempt from patentability is technological. It consists in creating hybrid organisms which cannot reproduce themselves. This would hinder customers, such as farmers, from reproducing the organism, and force them to do what patent law would equally have forced them to do, ie to buy new organisms. However, such technological strategies are being developed anyway.[79] If one wants to abate them, regulatory action is the more appropriate way. For instance, variety certification could be refused on the ground that hybrid varieties do not possess the necessary agricultural value (*landeskultureller Wert*) which is a precondition according to the German Seed Marketing Act.[80] Hybrid seeds, it is true, normally provide a higher yield, but if the same skill, time and money were spent on employing population improvement techniques in open-pollinated varieties as is done for heterosis, higher yield would probably be just as achievable.[81]

How then should patent law in the sphere of biotechnology be redesigned? I hesitate to suggest answers because my primary concern was to show that this is a question that needs to be addressed. This is not a mere doctrinal discourse, where new phenomena are subsumed under stretched old legal forms, nor is it a substantialist discourse where vitalists wage an idle war against materialist pervasiveness. Rather, it is a functionalist argument where patentability, as opposed to other policy alternatives, is assessed with regard to social, economic and ecological effects. Some preliminary ideas may nevertheless be presented. They concern patent law itself as well as flanking measures.

It is somewhat strange to realize that the requirements of patentability do not seem to reflect any of the above effects. One discusses novelty, non-obviousness, technicality (as opposed to givenness in nature), industrial applicability, description, disclosure, scope, exhaustion—all requirements which are devised to define the exclusive zone so that maximal progress (in the abstract, to be sure), but no undue monopoly (with its contra-productive effects on progress) results. Problematic socio-economic and ecological effects and their possible reflection in patent requirements are hardly debated, although a requirement does exist which may cope with such effects.

In the American Patent Act this requirement is called usefulness.[82] Although this could be interpreted to encompass problematical effects of a patent or to require a need for the invented product or process, the practice is, however, satisfied if the application describes some possible practical use. This is an easy hurdle for patent applicants.[83] Such weak interpretation of 'usefulness' comes close to the requirement in paras 1 and 5 of the German Patentgesetz and Arts 52 and 57 EPC which is that the invention must be industrially applicable (*gewerblich anwendbar*). During the first decades of the Patentgesetz of 1877, this clause (which then read 'industrially worthwhile' (*gewerblich verwertbar*)) was still discussed as one which required there to be a need (*Bedürfnis*), although need was soon degraded to mean anything which could be used.[84] The need or use had also to be 'industrial', ie a patented product must be industrially producible and a patented process industrially applicable. In former times, the sphere of the industry

[79] Kloppenburg (n64), 91–129. J. P. Berland, R. Lewontin, '*Breeder's rights and patenting life forms*' in Nature 322 (1986) 785–788.

[80] *Saatgutverkehrsgesetz*, para 34.

[81] Kloppenburg (n64), 93, 128.

[82] 35 USC 101.

[83] The somewhat stricter test required by the Supreme Court in 1966 (*Bremer v Manson*, 383 US 519), does not seem to have had much practical impact. See *Commercial Biotechnology—An International Analysis* (n63), 387. For a differing view see Moufang (n30), 294.

[84] See already Kohler (n3), 62 seq. For the present time see G. Benkard, *Patentgesetz*, 8th ed (1988), para 5 no 3.

was more narrowly defined, excluding agriculture, for example, whereas today more professions are included.[85]

The question which arises in our context is whether the concept of usefulness and industrial applicability should be revitalized and applied to the problematic effects of protecting an invention. I am not advocating a full-fledged need test. This would lead into difficulties of how and by whom needs were to be determined. But a more modest version of checking need may be worth considering, namely one where only agreed negative candidates are sorted out, as, for instance herbicide instead of herb resistance. One could also put in different degrees of usefulness which varied with the time period protected by the patent. This implies abandoning the principle that there is only one time period for every patent. As to the industrial applicability this could be understood to mean that a product or process has to be sufficiently developed and rather close to being marketable.[86] Basic research would then be freed from the suction of applied product development. Without patentability new information would more easily be exchanged including information about product and process risks to health and the environment.

One could also reconsider the more precise definitions of patent requirements and scope from a critical functionalist perspective. Inventiveness could be understood in such a way as to retard the speed of technology development, thereby improving the quality of the outcome. Going back to past definitions, one could postulate that only such processes are inventions and not discoveries, which can be repeated with almost the same result, and only such products, which can be precisely reproduced through recombinant techniques or breeding while natural reproduction would not suffice. A more modest version would be to define (patentable) microbiological processes more narrowly. For instance, instead of the EC Commission's broad definition[87] one could require a 'decisive technical factor' or that 'human intervention is a determining factor', as it was proposed by both France and Spain in the preparatory meeting for the Council decision.[88]

As to the effect of the patent the doctrine of exhaustion could be developed so that a farmer's exemption like that in the plant variety protection law is tolerated, if the patent (eg for a DNA sequence cutting across species) interferes with a plant breeder's right.[89] In addition, the research exemption in para 11 no 2 Patentgesetz could be broadly interpreted.[90] In particular, research which aims at a better understanding of the social, economic and ecological effects of the patented process or product should be unrestricted, even if the test is not exacted by a public research body but by a private firm.[91]

As to equity in the North–South relationship genetic resources should be regarded as

[85] See *Patentgesetz* sec 5 and Benkard-Bruchhausen (n84) para 5 nos 4, 5.

[86] This was the US Supreme Court's reading of the usefulness test, see 383 US, 519, at 534: 'Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field'.

[87] 'One or more steps of which at least one consists of more than selecting an available biological material and letting it perform an inherent biological function under natural conditions.' See proposal (n23) Art 7.

[88] EC Council Doc 4212/90 of 22 Jan 1990, Art 7.

[89] This has been proposed by the Law Committee of the European Parliament, see above n47.

[90] For such a broad understanding see Chroziel, *Die Benutzung patentierter Erfindungen zu Versuchs. Forschungszwecken* (1986), 148 seq.

[91] This is rejected by Benkard-Bruchhausen (n84) para 11 no 6.

a common heritage of mankind, nota bene not only with regard to access to the resources, but also as to the benefits drawn from them. This would not exclude the introduction of intellectual property rights on genetic resources. But these rights should be subject to 3 qualifications. First, indigenous farmers should have the right to plant back seeds developed on the basis of germ plasm from their own native plants.[92] Secondly, the states of origin of the genetic material should be granted free compulsory licences in order to allow their research institutions to make use of the invention for the benefit of the national economy.[93] Thirdly, income drawn from inventions derived from southern genetic resources should be shared with the states of origin. This could be done by means of an international fund as it is foreseen by the Rio Convention on Biological Diversity. Such funding scheme is preferable to bilateral compensation, because the fact that many northern inventions are based on genetic resources extracted from a greater number of countries and at former times can be reflected in the modalities of contributions to the fund[94] as well as in the destination of subsidies paid out of the fund.[95]

One last consideration concerns procedures. Developments in patent law and doctrine as applied to biotechnology have been heavily influenced by an inner circle of intellectual property lawyers and an outer circle of interest groups.[96] These circles have not only acted at state level, but have also succeeded in permeating the international level. For instance, the WIPO-UPOV interface expert group consisted of state as well as of pressure group representatives.[97] In a modern world where international law is influenced by non-governmental organizations there are no principled objections against this. However, such procedures must be balanced. The participating non-

[92] Some think of establishing a special protective regime for such 'folkseed' which would also yield income for the local communities. See the FAO Undertaking on Plant Genetic Resources of 1983, as endorsed by the FAO Conference of November 1989. This would coincide with proposals to create a protection for cultural folklore (see *Model Provisions for National Laws on the Protection of Expressions of Folklore against Illicit Exploitation and other Prejudicial Actions*, edited by WIPO and UNESCO. See also Keystone International Dialogue Series on Plant Genetic Resources, Oslo Plenary Session, Final Consensus Report. *Global Initiative for the Security and Sustainable Use of Plant Genetic Resources*, 1991). I believe that these proposals point into the wrong direction, namely privatization rather than common heritage. Besides, constructing a manageable legal frame for folkseeds is very difficult. Divising a fair concept of the property holder is almost impossible. No wonder that the model law on folklore left this open (see section 9 of the draft).

[93] The Convention on Biological Diversity which was agreed in Rio in June 1992 has failed to seriously tackle the problem of intellectual property protection for genetic resources. The text is contradictory. On the one hand access to and transfer of technologies that are relevant to the use of genetic resources 'shall be provided on terms which recognize and are consistent with the adequate and effective protection of international property rights' (Art. 16, para 2), on the other hand the Contracting Parties 'shall cooperate (. . .) to ensure that such rights are supportive of and do not run counter to the objectives of this Convention' (Art. 19, para 5).

[94] A draft prepared by IUCN had proposed a charge on plant variety and patent rights given for biological material developed out of primitive germ plasm which should be paid to the fund. Instead, the Rio Convention relies on contributions of the member states. The amount is not specified but an incentive to contribute results from the right of the developing country parties to refuse to provide genetic resources if the developed country parties do not effectively implement 'their commitments under the Convention related to financial resources and transfer of technology' (Art. 20, para 4).

[95] According to the Rio Convention the fund shall be committed to the preservation of biodiversity. Any state may apply for assistance, also those the territory of which may have provided genetic resources in some distant past but has lost its biodiversity since then. See Art. 20, 21 of the Convention.

[96] Hermitte (n53), 283 seq.

[97] See n22.

governmental organizations must reflect the complexity of affected interests, including environmental and consumer protection interests. As to the participating States, the less developed world must not only be invited, but also be given professional support, such that they can find their own way through the complex labyrinth of intellectual property law.