

The Protection of New Developments in the Field of Biotechnology by means of Patent and Plant Varieties Protection

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1. Fright and Prejudice

Biotechnology and genetic engineering like most other new technological developments are attracting special public attention, often even mingled with suspicion, fear and deprecation. The present symposium has probably dealt with this problem several times before. Therefore, from the German Patent Office's point of view I would like to concentrate on demonstrating that industrial property protection for biotechnological inventions represents the natural consequence of an almost 120 years' period of experience and evolution of the German patent system.

A historical view of the development of our patent system shows that patent laws have changed the concepts of what is to be considered patentable in accordance to the developments in science and technology. It was already in the last years of the past century that chemical inventions were considered patentable, and from the beginning of the current century the German Patent Office began to grant patents for fermentation processes and similar inventions that dealt with biological phenomena, as soon as these fields of technology became sufficiently describable, controllable, and industrially applicable. Today, biotechnology can be considered a field of technology that is describable, controllable and industrially applicable like the "classical" fields of technological inventions that are familiar to everybody, such as the fields of physics or engineering. The one special feature that makes biotechnology appear so frighteningly different in the eyes of the public, the fact that it deals with living material, does not make much difference to patent law. There have, of course, been certain modifications in patent law corresponding to the fact that living material is self replicating and subject to mutations which made it necessary to redefine certain requirements of patentability i.e. description, clear and concrete disclosure and repeatability of the invention. Yet, from the point of view of patent protection, there is nothing unusual, strange or demonic about granting patents for biotechnological inventions. Patent law considers and always considered patentable

those inventions that aim at a production of goods, and biological inventions that have been patented and will be patented in the future certainly meet this requirement. Fright and prejudice that often prevail in public discussion cannot hinder a patent lawyer from considering the new technologies as what they are: Means of production that have to follow the very same legal regulations as any other such means.

2. The basic principles of Patent Law

At this point one might ask why a lawyer who has studied neither biology nor medicine can see the field of biotechnology so cool-headedly. The general answer is very simple: The Law applies equally to everyone and to everything, as long as the cases are equal. In the case of biotechnological inventions the need of protection for the inventor as well as the other benefits of granted patents are the connecting link that make inventions in the field of living material "equal" to other inventions in the view of patent law.

In order to give a better idea of this concept I would like to give an overview on the purposes and objectives of the patent system which in Germany has stood the test of time for almost 120 years.

Our patent system like the other modern patent systems is based mainly on two central ideas: First, the authors of a progressive technology, i.e. the scientists and inventors, shall be given a fair reward for their achievements; secondly, technical progress shall be promoted.

The Patent Law recognizes that the authors are entitled to the results of their creative technical activity. Therefore, the inventor is granted an exclusive right within the term of the granted patent. During this period of time, only the inventor has the right to dispose freely of his invention. He can decide what is to be done with his invention, whether, how and by whom it is marketed and exploited, and whether he himself makes use of it or authorizes others to use it by a licence and receives royalties for the privilege he grants. Any third person not having the explicit consent of the patent holder is prohibited from using the invention and, in the case of infringement, liable to damages. This applies to direct use of the invention i.e. supplying or importing of a patented article, as well as to indirect use by supplying means relating to an essential element of the invention.

Besides this desirable recognition of the inventors achievement which is also meant as an incentive for inventive activity of the individual there is another key aspect to the understanding of patent protection in general: In return for the protection and recognition granted to the inventor, the patent law requires the invention to be made accessible to the public. This is a basic difference between modern patent law and the sovereign privileges. In former times, these granted exclusive rights to inventors and enabled them to use their inventions while keeping their technical knowledge secret. Modern patent law, on the other hand, is oriented towards the demands of technical

progress in the interest of public welfare by means of an early publication of the new technical knowledge.

Technical progress is promoted by the interaction of these two basic principles of patent law: The incentive for the inventor by securing a fair reward, on the one hand, and the promotion of technical knowledge by means of an early publication, on the other hand. If the inventor can rely on the secure exclusive use of his invention for a given period of time, he does not have to keep his knowledge secret. From the angle of economic policy and public order, this implies several advantages for the inventor as well as for his competitors and not least also for the public.

If an inventor keeps his new superior technical knowledge a secret aiming at securing his exclusive position, he is always in danger of losing this competitive lead — based on secrecy — when protective rights of others emerge. These rights can impede his own options of development, because inventions that are kept secret are not protected by an officially guaranteed right but can be secured only on the basis of individual private agreements with all the risks of violation and illicit non-disclosure.

Publication of inventions offer advantages for the competitors not only because they are informed about legal risks they might run by unknowingly infringing others' rights; they also get to know the most recent state of the art and, hence, are able to use this knowledge for further developments. This is, obviously, an essential objective of the patent system. When new developments are published in good time, the competitors also obtain significant advantages, since they are able to decide early on their own developments or on licence arrangements with the patent holders.

Finally, from the point of view of the public, the publication of inventions is significant with regard to the following aspects: In countries like Germany that have only few natural resources, technical know-how, the innovative potential, is one of the most important resources of the economy. An effective system of industrial property rights is able to provide an optimum use of these resources by the double mechanism of securing a fair reward and of publishing the results of new technological developments. Publication can set the general legal conditions for use and further development, it can influence desired and undesired directions of the development. This is not possible when technical developments take place in secrecy.

I shall come back to this aspect later because I consider it particularly significant with regard to the public discussion on patent protection for biotechnological inventions.

3. The present state of protection for biotechnological inventions

After this fundamental definition of the relation between advance of technology and patent law, I would like to describe the present state of protection for biotechnological inventions through patent law and plant varieties protec-

tion by outlining the development of the relevant system of protective rights.

At the beginning of my lecture I have pointed out that today's considerations on patent protection for microbiological inventions represent a consequence of the general principles of patent law. What in a retrospective view is true has, however, not always been the prevailing sight of the issue.

After several decisions of various patent offices in Germany and abroad on granting patents for biological inventions, the Supreme Court of Germany in 1922 explicitly confirmed the opinion of the Patent Office ruling that also such methods could qualify for patent protection which were based on the biological processes of nature. Patents had already before been granted by the Office for certain treatments of biological substances like yeast as well as for the production of certain substances by biological processes such as antituberculosis serum. Since the thirties, the Patent Office developed the practice of patenting also plant varieties. However, for this practice there was no secure legal basis. The patent laws since 1877 until the Amendment of Patent Law of 1967, did not contain any explicit provision with regard to biological inventions, and the Patent Office's practice had not further been consolidated by court decisions. This changed with the famous "Red Dove" decision of the Federal Court of Justice of 1969. The Federal Court explicitly recognized in this decision that the planned exploitation of biological natural forces and phenomena is not principally excluded from patentability. In this specific case, no patent was granted for the filed breeding result, i.e. the red dove, because the application lacked a description of a reproducible process that would lead to a genetically identical result. Nevertheless, according to this decision, the principle was established that animal and plant breeding processes and the results thereof, consequently also animal and plant varieties as well as microbiological processes and the products thereof could be regarded as patentable. In 1975, in its "Baker's Yeast" decision, the Federal Court of Justice dispensed with its stringent requirement of a description of the reproducible invention leading to a genetically identical result. In case of the claims directed at microbiological processes, the Federal Court of Justice accepted in addition to the written description the deposit of microorganisms as basic material for processes.

Finally, in 1987, the Federal Court of Justice accepted the deposit in addition to the written description also for such claims that were directed at microorganisms per se. Thus, for the grant of a patent in the field of biology it is now sufficient to make a newly-bred individual organism available to the public. After all, the practice of granting patents applied at the Patent Office and especially the court decisions of the Federal Court of Justice have extended — in parallel to the technical development — the term of patentable technical inventions to the field of living organisms and modified the principles of disclosure of the invention according to the special conditions of such inventions.

4. Patent Protection vs. Plant Variety Protection

The trend in the practice of granting patents and in court decisions, however, has been met with a counter development from the fifties onwards.

In 1953, the Varieties Protection Law was introduced as a special form of industrial property protection in the field of plant varieties. This was owing first to the lack of a concept of securing the protective requirements for the patent, that is descriptibility and reproducibility of the invention, with respect to plant varieties; secondly, to the fact that many results of breeders activities do not meet the required level of invention. So, the introduction of Varieties Protection aimed at meeting the need of protecting this innovation. In the following years, however, the idea of a varieties protection law developed its own dynamic force neglecting the new developments of patent law, for instance, the idea of the deposit. On the contrary, a tendency towards delimiting these two protective rights became visible. This led to a partial exclusion from patentability of certain biological inventions.

The Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention of 1963 leaves it to the discretion of the Contracting States, among them the Federal Republic of Germany, to exclude from patentability plant varieties and breeds of animals and essentially biological methods of breeding animals and plants. The Strasbourg Convention, on the other hand, makes provision that general requirements should remain for microbiological inventions i.e. that patents may be granted for all inventions which are new, involve an inventive step and are industrially applicable. Up to this Convention the exclusion of plant varieties and breeds of animals as well as the essentially biological methods of breeding animals and plants was not considered conclusive from the legal point of view. On the contrary, in Germany as well as in other countries, correspondent patents had been granted before. In the sixties, however, the idea of a special system of protective rights in the area of plant varieties gradually gained acceptance.

In accordance with international agreements, in particular with the International Convention for the Protection of New Varieties of Plants of 1961, the Federal Republic of Germany introduced the Plant Varieties Protection Law and at the same time limited the patentability of plant varieties under the Patent Law. In 1967, this limitation was extended to breeds of animals. Thus, according to the present state of German patent law, which in this respect corresponds in substance with the European Patent Convention, plant varieties and breeds of animals as well as essentially biological methods for breeding plants and animals are excluded from the area of biological inventions. Furthermore, the area of biological inventions is restricted by another provision of Patent Law which regards methods for treatment of the human body by surgery or therapy and diagnostic methods practised on the human or animal body as inventions not susceptible of industrial application and thus excluded from patentability. This exclusion which corresponds with the European Patent Convention obviously affects a field in which biotechnology is of particular importance.

Apart from the actual exclusion from patentability of certain biological inventions, however, it is today at least settled that inventions in the area of nature are on principal patentable, as soon and as long as they meet the usual requirements for patentability. The tendency of court decisions of biological inventions since the "Red Dove" decision has been confirmed by law and followed by the practice of the Patent Office.

This practice, however, can still lead to overlapping spheres of protection of patented biotechnological inventions and of plant varieties protection in cases where by effort of a breeder a genetically manipulated plant (which is patented as the result of a process patent) has become a stable variety which is now subject to plant variety protection. Until its revision in 1981, the International Convention for the Protection of New Varieties of Plants stipulated that double protection with regard to protected plant varieties, i.e. patent protection and varieties protection, was not admissible. This ban of double protection no longer exists, and rightfully so, for we must not forget that Plant Variety Protection had been introduced in the fifties and sixties in order to provide protection for certain innovations for which patent protection did not fit at the time. In the meantime we have made patent law fit for many biological inventions, so it was time to think the issue over.

Nevertheless, there is a need for clearly delimiting the two protective rights in practice. In general the buyers of plants protected under the Varieties Protection Law are farmers. There seems to be a European consensus about the fact that farmers should be spared the trouble to deal with two protective rights, i.e. with requests for two different licences. Therefore, a solution for the practice is to be sought in order to make sure that with respect to protected plant varieties the consumer is faced with one protective right only, even when the variety he uses is based on an invention in the field of genetic engineering. The following idea could possibly provide a solution: The first invention, i.e. the invention leading to a genetically manipulated plant, is protected by patent law. This right extends to all subsequent generations, since the patentees title would otherwise be exhausted merely by the natural biological process. The incentive effect would become void. However, the right derived from the patent could be exhausted, if the patent holder authorizes a third party by a licence agreement, for instance, to breed a variety based on the genetically manipulated plant while securing himself a fair remuneration for the invention. This second invention would be subject to protection and remuneration under the Varieties Protection Law. This, however, has not yet been regulated in this way by law.

5. The effects of patent protection

After describing patentable subject matter, I would like to finish my lecture with some more remarks on the effects of a patent, because in this field certain misconceptions seem to prevail.

The patent belongs to the area of intellectual property. Just like other property rights, the patent, too, gives the owner the authority to exclusively dispose of his right and to exclude others from using it. As I have already mentioned, this exclusive right of the patent holder enables him to use his invention either by exploiting it himself or by authorizing third parties through licences. Patents can also be assigned to third persons just like other rights.

The use of the patent, however, either by the inventor himself or by a licence holder, is still and always subject to general legislation, to public order. In the past years public discussion focussing on inventions in genetic engineering frequently failed to notice this aspect which applies to biotechnology no less than to any other field of technical invention. The right obtained by the governmental act of granting a patent may — like any other right of the individual — only be executed within the boundaries of the legal system. The owner of a patent regarding a new fire arm, for instance, obviously is not entitled to use an arm manufactured according to his patent just in any way he likes. His use of the arm has to follow the general legal provisions on the use of fire arms. This example should make it clear: A patent does not grant an unlimited right to make use of the respective invention. And what is true for fire arms applies as well to biotechnological inventions. The use of these has to follow the general legal provisions. If anything in this field at all, these provisions should be discussed, but not the question whether patents should be granted. The legal provisions decide on the use which an inventor may make of his invention. And this is where an essential advantage of patent law becomes manifest: Owing to the fact that the public is informed at an early date about inventions which are filed for patent application, society is capable of adjusting to new developments and creating the necessary legal and social framework for the application of a new technology.

Therefore, to me the conclusion is obvious: Patents contribute essentially to the aim of making inventions safe and secure — for the inventor who receives a fair reward for his invention as well as for society that participates in the increase of knowledge and can keep legal control of the use of the invention.

After almost 120 years of experience with our patent system we can say that although patent law will always be subject to improvement and adaptation there is no better legal instrument in sight to meet these objectives. If we succeed in making this idea clear to the public we certainly shall arrive at an understanding of granting patents to biotechnological inventions that is characterised not by fright and prejudice, but by common sense and legal sensibility.

Ochrona osiągnięć biotechnologicznych

Streszczenie

W artykule przedstawiono sytuację prawną w zakresie ochrony osiągnięć biotechnologicznych przez patenty oraz ochronę odmian roślin. Omówione zostały podstawy prawne systemu ochrony własności intelektualnej w Niemczech (z krótkim rysem historycznym) oraz perspektywy.

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