Max Planck Institute
for Innovation and Competition

The Scope of Protection – Spotlight on the ‘Why’

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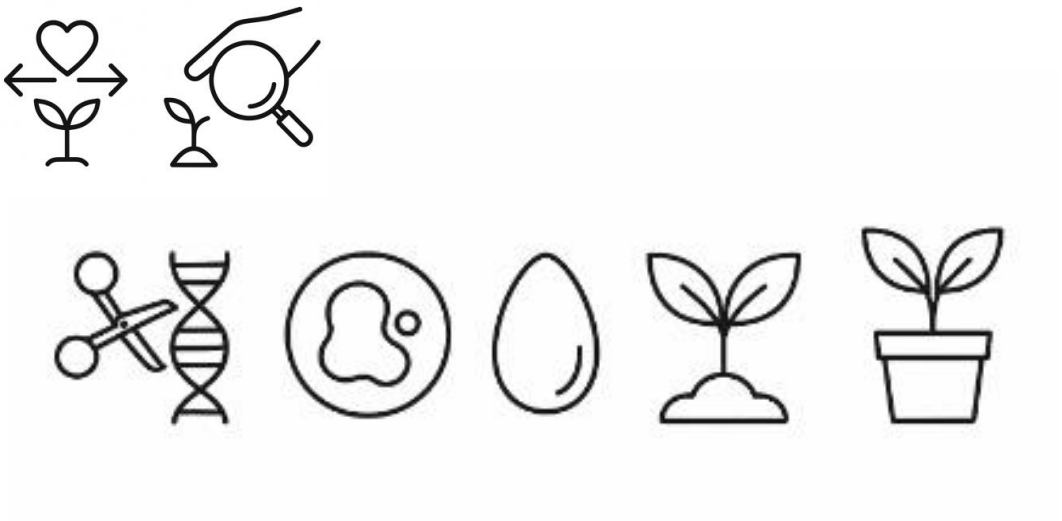
25 June 2025

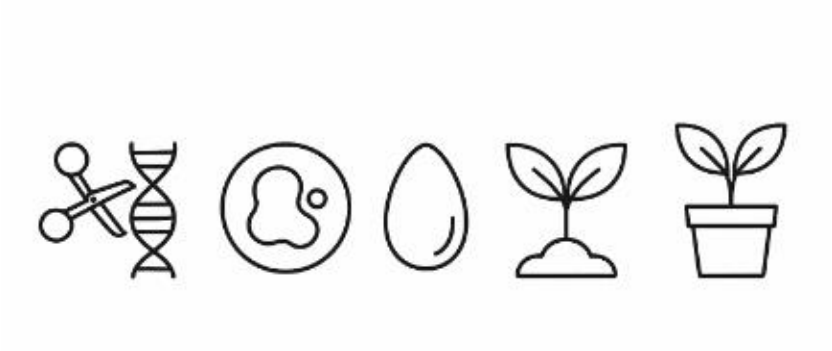
The scope

- Ideally
  - balance
  - commensurateness
  - consensus

The scope of protection for biological inventions



Biological inventions



- baseline: art 8 & art 9 Biotech Dir
- historically…
  - ‘specific characteristics as a result of the invention…’
  - protection for process → (any) product
- interpretative challenges
  - absolute? purpose-bound?
  - exhaustion?

WIPO

BIOT/CE/III/2
ORIGINAL: English
DATE: April 8, 1987

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

INTERNATIONAL UNION FOR THE PROTECTION OF INDUSTRIAL PROPERTY
(PARIS UNION)

COMMITTEE OF EXPERTS
ON BIOTECHNOLOGICAL INVENTIONS AND INDUSTRIAL PROPERTY

Third Session
Geneva, June 29 to July 3, 1987

75. Observations by the International Bureau on Paragraph 74. If the subject matter of a patent is a process for the production of living matter or other matter containing genetic information permitting its multiplication in identical or differentiated form, any protection conferred by the process patent to the product obtained by the process should not only extend to the product initially obtained by the patented process but also to the identical or differentiated products of any subsequent generation obtained therefrom, the said products being deemed to be products obtained directly by the patented process.

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9. The Delegation of the Federal Republic of Germany thanked the International Bureau for the excellent working document and for the elaboration of the two questionnaires. It expressed the view that the aim of the present session of the Committee of Experts should be the assessment of an appropriate and effective protection for new innovations in the field of biotechnology. In view of the ever-growing importance of this area of technology, the questions concerning the granting of patent protection were becoming more and more pressing and the initiative of WIPO in this connection was very much appreciated. Most of the solutions proposed in document

147. In this connection, it was stated that appropriate and adequate protection should be developed for biotechnological inventions as research and development in this field of technology required costly investments. As had been demonstrated in the statements put forward by interested circles, the present legal situation in many countries concerning the protection of intellectual property in biotechnological inventions was unsatisfactory. It was felt that, in order to close existing gaps in the legal systems for the protection of biotechnological inventions, a mere re-interpretation of provisions currently in force would not be sufficient. Deficiencies in the protection had to be identified and in-depth studies had to be made in order to find solutions that were tailor-made in respect of innovations dealing with living material. In addition, a number of ethical and political problems had

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13.12.1995
COM(95) 661 final

IMPACT OF THE PROPOSAL ON BUSINESSES (and particularly SMEs)

2. WHICH INDUSTRIES WILL BE AFFECTED?

(a) The measure will benefit manufacturers of biotechnological products, and particularly firms that base their activities on research.

(b) According to a study published by Ernst & Young in 1995, 485 firms would be affected in Europe. Of those, 81% employ less than 50 people, and 45% were founded after 1986. They cover a wide range of activities: pharmacy, chemicals, agriculture, foodstuffs, the environment and plant. While investment in the research and development of new biotechnological products is high, the return on that investment is
system of patents fo
technology. The propo
biotechnology, whatev

(B) ON INVESTMENT AND THE ESTABLISHMENT OF NEW BUSINESSES

Harmonization of legal protection for biotechnological inventions should enable the firms concerned to feel far more certain about recouping their costs and investment. Once it is clear that patent law also applies in full to biotechnological products, patent holders will realize that the possible return on sums invested in perfecting such products enjoys a much greater legal guarantee. Patent law does not, of course, guarantee that there will be a market for any given product, but at least research findings cannot be turned to advantage by those not involved in making the necessary initial investment. This is a powerful incentive for setting up new businesses in order to undertake leading-edge research in biotechnology and then market the results. The sector's great promise is borne out by Ernst & Young's figures, which show that many of the firms concerned are newly established and small.

Incentive/investment protection rationale

(2) Whereas, in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;

(3) Whereas effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;

Why are patents necessary in the area of biotechnology?

Patents provide an incentive to innovation. Without the safeguard provided by patents, industry and other inventors would be unwilling to invest their time and money in research and development. This applies to biotechnology as well as any other area of technology. Indeed given the considerable amount of high risk investment that is often required in the area of biotechnology, particularly in the field of genetic engineering, adequate patent protection is even more essential to encourage the investment required to create jobs and maintain the European Union's competitiveness in this crucial field. Indeed, the key role of adequate patent protection in the creation of a dynamic; knowledge based economy was explicitly underlined by the March 2000 Lisbon Summit conclusions.

EUROPEAN
COMMISSION

Brussels, 29.4.2021
SWD(2021) 92 final

4.8.2 Intellectual property

With regard to IP and the patent protection of biotechnological inventions (under Directive 98/44/EC[54]), many Member States and stakeholders in the agricultural sector acknowledged the benefits and opportunities of patenting NGTs and their products. They noted that a strong pa
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On the other hand, many Member States and stakeholders expressed concerns with regard to patenting or accessing patented NGTs or NGT products, in particular for SMEs. These include the limiting effects of such patents on access to new technologies, and plant breeders' access to the genetic material they need for further innovation in breeding, especially if compared with plant variety rights[55]. Other concerns related to the concentration of players on the seed market, resulting in higher seed prices, a reduced choice in seeds and greater dependency among farmers. Also mentioned were the high costs and complexity of patenting, licensing patented products and other aspects such as 'freedom to operate' analyses, e.g. due to the complex patent landscape of the

All responding stakeholders from the pharmaceutical sector and some Member States mentioning this sector see benefits in strong patent protection of NGTs and NGT products as a pre-requisite for innovation due to high R&D costs, but some express concerns about the complex patent landscape for NGTs, with many players holding patents and uncertainty as regards the IP situation. A few Member States expressed concerns about the affordability of gene therapies. One noted that the potential higher prices for such therapies may not be linked to their actual production cost, but result from patents.

EUROPEAN
COMMISSION

Brussels, 5.7.2023
SWD(2023) 412 final

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Directive 98/44/EC on the legal protection of biotechnological inventions, European Patent Convention and Regulation (EC) No 2100/94 on Community plant variety rights – The genetic modification made in a plant by means of a NGT is patentable, as well as the technique used to obtain the modification. Plant varieties obtained by NGTs can be protected by Community plant variety rights (CPVRs). In this regard, a balanced intellectual property system, including patent protection, is essential for innovation in agricultural biotechnology, i.e. by incentivising investments in research and development and promoting the dissemination of knowledge. At the same time, concerns have been raised by many stakeholders (farmers, breeders, in particular from the GM-free and organic sectors) on the possible proliferation of patents on NGT plants in the future and on potential claims being made by patent holders on conventionally bred plants that cannot be distinguished from NGT plants, fearing that this scenario could be further exacerbated if NGT plants are not subject to a GMO authorisation. While from the legal point of view the NGT initiative is independent from the rules on the protection of intellectual property and does not address matters relating to the application of the IPR legislation to GMOs, in particular to NGT plants, the Commission has taken note of the concerns brought forward by certain stakeholders on the need to ensure in particular the accessibility of farmers to patented seeds and of breeders to patented genetic material, and will carefully consider them.

‘U-turn’: EP’s proposal of 7 Feb 2024

Amendment

(45a) The European Parliament has called for the Union and its Member States not to grant patents on biological material and to safeguard the freedom to operate and the breeders’ exemption for varieties. It should be ensured that breeders have full access to the genetic material of NGT plants, which by definition are not transgenic plants. Access to genetic materials can best be secured when the right of patent holders is exhausted in the hand of the breeder (breeder’s exemption). As current provisions in patent law do not provide for a full breeder’s exemption, it should be ensured that patents should not restrict the use of NGT plants by breeders and farmers. Hence, NGT plants should not be subject to patent legislation, but should for the protection of intellectual property solely be subject to the Community Plant Variety Rights (CPVR) system, as laid down in Council Regulation (EC) No 2100/94, which allows the use of the breeder’s exemption. NGT plants, their derived seeds, their plant material, associated genetic material such as genes and gene sequences, and plant traits should therefore be excluded from patentability. The exclusion from

Amendment

Article 4a

Exclusion from patentability

NGT plants, plant material, parts thereof, genetic information and the process features they contain shall not be patentable.

‘U-turn’: EP’s proposal of 7 Feb 2024

2. In Article 8, the following paragraph is added:

‘3. By way of derogation from paragraphs 1 and 2, the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall not extend to biological material possessing the same characteristics that is obtained independently of the patented biological material and from essentially biological processes, or to biological material obtained from such material through propagation or multiplication.’

3. In Article 9, the following paragraphs are added:

'2. By way of derogation from paragraph 1, a plant product containing or consisting of genetic information obtained by a patentable technical process shall not be patentable if it is not distinguishable from plant products containing or consisting of the same genetic information obtained by an essentially biological process.

3. By way of derogation from paragraph 1, the protection conferred by a patent on a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.

4. The protection conferred by a patent on a technical process that enables the production of a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.'.

Dual nature of exclusive rights

- enabling technologies
- policy dilemma
- balance or trade-off?

Underutilisation

- multiple inputs jointly required to realise value
- coordination challenges
- ‘too difficult’

Can Patents Deter Innovation? The Anticommons in Biomedical Research

MICHAEL A. HELLER AND REBECCA S. EISENBERG Authors Info & Affiliations

SCIENCE • 1 May 1998 • Vol 280, Issue 5364 • pp. 698-701 • DOI: 10.1126/science.280.5364.698

Limitations on the exercise of rights

- systematic solution?
- incentive?
- mandatory aspects of new proposal

Outlook

- Principle- and evidence-based law making