Economic Insights and Deficits in European Biotechnology Patent Policy

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The decisive statutory provision of the EU for patent protection of genetic engineering inventions is the so-called directive on biotechnological patents (DBP). Its objective is the encouragement of research and development in the genetic engineering sector. The following exposition shows that the DBP has two major flaws from the economist's point of view, under which particularly small and medium-sized enterprises, the driving force of this young line of business, suffer.

It is a primary task of government institutions such as patent laws to guarantee property rights and to maintain competition to enhance efficiency based upon the market (for ideas). At the same time the support of special economic interest groups and the limitation of other activities should be avoided. The patent law is a major, vital pillar of regulatory policy and helps support the government objective of sustaining high levels of innovation. The grant of a patent converts an invention into a judicial good and thereby establishes intellectual property that is worthy of protection. At the same time incentives for research and development (R&D) arise, as the patent bestows the right on the inventor to exclusively use and commercialize his or her invention. The attainable monopoly rents make R&D attractive as a strategy in competition. Conflicting goals are unavoidable simply because scarce resources are now directed into certain areas and are missing elsewhere in the R&D system. In addition, inventors are often restricted in their further developing of existing ideas due to prevailing exclusive patent rights. Therefore, patents may often hinder both intertemporal efficiency and welfare.

Discussions on the topic have commonly been quite controversial. Important questions have emerged such as whether, and for which life science, the patent protection of inventions should generally be granted and how far this protection should reach. The EU directive of 1998 on biotechnological patents is an attempt to address the various trade-offs and dimensions involved.

The goal of this article is to analyse the effectiveness of the directive on bio-patents from the point of view of economics and to query how far it does justice to its own objective of encouraging R&D, without questioning this objective itself.[1] To begin with important theoretical elements are described, from which the decision-making problem for economic policy in structuring the optimal patent system can be derived. The directive on bio-patents, as the decisive legal foundation, is then elucidated and it is shown for which kind of invention it grants patent protection. Finally, the flaws of the directive, which stand in the way of the fulfilment of its own goals are described.

Economic Foundations of Patent Theory

Genetic sequences, the key to widely differing characteristics of living organisms, are a prime example of a public good where the principle of rivalry fails. Genetic sequences are knowledge goods. Once the sequence is known the marginal costs of additional usage are nil. Society's optimal allocation of a genetic sequence, and knowledge assets in general, is obtained when the specific information is available to every interested consumer at no cost. From the point of view of economic welfare and efficiency, the non-validity of the principle of rivalry requires that no-one should be excluded because of positive prices. The more individuals and enterprises apply the existing genetic information positively (e.g. for the implementation of new medical therapy and

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[1] The DBP provides in its opening words – almost inconspicuously – an explanation for the patent protection of biotechnological inventions, namely that R&D can only be profitable in this area given adequate patent protection (2nd consideration DBP), thus assuring the maintenance and encouragement of investments in the genetic engineering sector (3rd consideration DBP). The description does not seem spectacular and in the literature which deals with the DBP it actually receives hardly any attention. In economic terms it certainly is essential for the issue of the costs and benefits of patents. On the discussion of the permissibility and necessity of government support for innovations cf. e.g. M. H. Dunn: Wachstum und endogener technologischer Wandel, in: ORDO, Jahrbuch für die Ordnung von Wirtschaft und Gesellschaft, Vol. 51, 2000, pp. 277-299.

medication), the higher will be the total social utility and benefits derived from new genetic treatments and commodities. If the prerequisite of a zero price is fulfilled, then static efficiency is obtained, i.e. existing genetic sequences are optimally used.

Following the usual assumption of profit maximisation the production and study of new genetic sequences by private companies is commonly ruled out under such given conditions. The possible welfare gain of society does not play any role in the individual decision-making of the enterprise. With a price equal to zero, innovative research projects on new genetic sequences and the production of new genetic products will not take place. The consequence is that dynamic efficiency will not be achieved. To overcome this dilemma the government may intervene. The government has the possibility of granting an exclusive usufruct for this knowledge good to the successfully researching enterprise via the definition and application of property rights, such as patents.

Among other things, one of the major economic characteristics of a patent is its duration, i.e. the length of its legal validity. The shorter the duration in which the patent holder can realise his exclusive right of disposal, the closer society comes to meeting static efficiency requirements, but there can be a faster reduction of dynamic efficiency at the same time. On the other hand a longer period of patent duration can stretch out the temporary monopoly rents of the patent holder and the incentive for developing new genetic sequences and applications. At the same time a longer patent duration may prevent the extensive use of the technology if the patent is applied as a barrier to market entry. With the definition of temporal property rights an economic trade-off between static and dynamic efficiency inevitably arises. It is the task of politics to alleviate this dilemma. An optimal patent guarantees the minimal pecuniary attractiveness necessary for the inventor, so that there are just enough incentives to become active in R&D. An optimal patent, from society's perspective, can be found when the marginal utility of the increased R&D activity equals the marginal costs of the monopolistic use. The second important dimension of creating a property rights system is the width of a patent. The width refers to the extent of application of a patent, i.e. the extent of the effective protection.[2] The question is whether similar ideas evolve which violate the already existing exclusive usufruct of the patent holder. A trade-off situation occurs in the same way when it comes to the regulation of the optimal patent width.

The Emergence of the DBP

The decisive legal foundation for patent protection in the field of genetic engineering in the EU is the "Directive 98/44/EC on the legal protection of biotechnological inventions"[3] (often referred to as the directive on biotechnological patents, in the following DBP). On July 6, 1998, the European Parliament and the Council passed the DBP after a ten-year debate. Its objective is the alignment of the national patent laws in the biotechnology sector. The individual patent laws of the member states will remain valid in the future. The DBP standardises the most important principles without creating an entirely new patent law for biotechnological and genetic engineering inventions. It does not aim for a restructuring of patent practice, but for a harmonic elaboration of the current law.[4] It should be clearly defined what is patentable and what is not, as well as in which areas patent protection should not be granted for ethical reasons.[5] Both the individual member states and the European Patent Office should have brought their specific legal bases into line by July 30, 2000,[6] but many member states have yet failed to do so.

Concept and Subject of Inventions in the DBP

Biotechnological inventions are patentable if they are clearly distinguishable from mere discoveries, which are not patentable. With regard to biological materials, e.g. genes, it was long disputed whether

[2] Definitions vary in detail.. Cf. e.g. P. Klemperer: How broad should the scope of patent protection be?, in: The RAND Journal of Economics, Vol. 21, No. 1, 1990, pp. 113-130.

[3] In addition to the DBP there is the established European Patent Convention (EPC), under which the European Patent Office has granted patents until now. This underlying agreement contains passages concerning, especially, genetic engineering, which will not be considered in this article as the DBP will be decisive for the new legal environment in the future. Furthermore, the EPC describes the procedure for registration and recognition of an invention. The inventor can decide afterwards if he wants to contact individual national patent offices or the European Patent Office in Munich. Registration at the European Patent Office makes a parallel registration at other member state patent offices unnecessary because a national patent is invalid parallel to a European one. However, with the registration at the European Patent Office no initial European patents originate, but Europe-wide identical national patents. Legal effectiveness and legal constancy go by the - possibly harmonised – national law.

[4] C. Luttermann: Patentschutz für Biotechnologie. Die europäische Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen, in: Recht der internationalen Wirtschaft, Vol. 44, No. 12, 1998, pp. 916-920.

[5] Above all the DBP regulates some basic procedural measures for the registration of a patent, which is not discussed further here.

[6] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, in: Official Journal of the European Communities, L 213, Vol. 41, 1998, pp. 13-21.

these were inventions or discoveries. It was argued that this material already existed in nature and only needed to be discovered, so that patent protection was not permissible.[7] The DBP settles this dispute: biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature. Here it is not significant that something unknown has been discovered but that a new technical theory on the deployment of natural biological forces is formulated and used to achieve a result the causality of which is clear. It is important that there is a contribution to the progress of technology originating from human beings. It must not be possible for the laws of nature alone to achieve the same result.[8] The DBP differentiates between two patentable inventions: products which consist of biological material or contain it, and processes by means of which biological material is produced, processed or used. Biological material has to contain genetic information and be capable of reproducing itself or being reproduced in a biological system.[9] Genetic products are thus mainly individual genes. Patent protection also includes products containing genetic information and all substances which are produced by means of genetic information, i.e. including living beings and their offspring. Biotechnological processes are techniques which are used for the isolation, transmission and specific activation of a gene. Beside this differentiation between products and processes there are no other differentiations in the DBP.

No Differentiation between Basic Knowledge and Application

Many innovations are the result of cumulative development processes, in which a fundamental discovery is either the basis for deriving a variety of applications or the impetus for a new line of research. For example, the development of the steam locomotive in the year 1803 was only possible after the previous invention of the principle of the steam engine. The transistor can be taken as an example of the triggering of a new line of research, which has ultimately led to today's powerful microchips. "Although a basic invention may have trivial value by itself, it may also be a technological breakthrough in that it generates great spillovers in the form of improvements likely to be far more valuable than the basic invention itself".[10]

If politics wants to decide upon the optimal duration and width of patents for basic innovations and inventions, it has to include initial cost and welfare elements in its calculations as well as inherent cost elements which would not exist in the case of an application innovation. On the profit side, the self-value of the basic invention has to be considered as well as the value of possible further developments. On the cost side, the patent will prevent the use of the patented idea as an input for further developments by competitors to a certain degree corresponding to the width of its validity and for a certain period of time corresponding to its duration. The existing patent thus does not encourage additional innovation, but prohibits any further advancement. The simple differentiation between products and processes in the DBP does not take into account these additional social costs and assumes a one-shot race instead of an innovation sequence. The optimal patent protection then tends to be too large for such innovations with development potential (e.g. genes).[11] However, the consequently necessary weakening of the exclusive rights of the patent holder will reduce private profits and therefore private R&D performance. Basic innovation which does not take place cannot generate advancement either. Therefore, the social costs which occur later in the form of absent, reduced or delayed subsequent inventions should not be taken into account in the determination of optimal research incentives. Each single invention in an innovation sequence must accordingly be seen as a one-shot race.[12]

There are two answers to this opinion. Firstly, an expansion of the patent's duration has a different effect on the described loss of welfare as compared to an expansion of the patent width. The minimal level of incentive necessary to attract an inventor is not dependent upon whether a single or basic innovation is regarded. But the choice between the two

[7] T. Kienle: Die neue EU-Richtlinie zum Schutz biotechnologischer Erfindungen - Rechtliche und ethische Probleme der Patentierung biologischer Substanzen, in: Europäisches Wirtschafts- & Steuerrecht, Vol. 9, No. 5, 1998, pp. 156-162; Directive 98/44/EC, op. cit., Article 3, para. 2.

[8] C. Luttermann, op. cit., p. 918.

[9] Directive 98/44/EC, op. cit., Article 2, para. 1 (a).

[10] H. F. Chang: Patent scope, antitrust policy, and cumulative innovation, in: The RAND Journal of Economics, Vol. 26, No. 1, 1995, pp. 34-57.

[11] V. Denicolo: The optimal life of a patent when the timing of innovation is stochastic, in: International Journal of Industrial Organization, Vol. 17, No. 6, 1999, pp. 827-846; R. Gilbert, C. Shapiro: Optimal patent length and breadth, in: The RAND Journal of Economics, Vol. 21, No. 1, 1990, pp. 106-112.

[12] T. Eger, P. Weise: Innovation, Imitation und Patentrecht im Systemvergleich, in: H. E. Gramatzki, F. Klinger, H. G. Nutzinger (eds.): Wissenschaft, Technik und Arbeit: Innovationen in Ost und West, Kassel 1990, VWL-inform, pp. 107-133.

instrument variables, patent duration and patent width, is based upon whether R&D in one technological area is a one-shot or a multiple-shot game.[13] To ensure optimal patent protection from a macroeconomic perspective, the interaction of both dimensions has to be carefully considered. The question arises as to the proper structure for a patent while holding the overall reward constant. The balancing of ex ante incentives and ex post costs occurs not only by controlling absolute magnitudes of the benefits for the inventor, but also requires an optimal fit and structuring of such benefits as a combination of the duration and the width of the patent.[14] If technical advancement is desired then genes as inventions should always be protected by a narrow patent with a long term of validity, so that everybody has the possibility of using this basic knowledge for further scientific and commercial advancement.[15]

Secondly, there is the possibility that the investor extends the original idea him-/herself, and thus evaluates the invention higher than in a one-shot view. If an optimal protection right is to be granted which supplies the minimal necessary incentive for R&D, the value of potential subsequent developments has to be considered.

Another significant connection has to be taken into consideration which complicates the political decision problem even more. If a researching enterprise makes a fundamental discovery and if that enterprise recognises the ensuing possibilities, then it may try to develop the initial idea further before the invention is patented and is compulsorily published by the patent office. The enterprise will first make an effort to establish a "first-mover" advantage over its competitors in the further development of the invention. From society's viewpoint, this will cause an undesirable waiting period because an existing useful innovation is not immediately applied and further implementations are postponed. According to Matutes et al. "... scope protection [meaning a patent with great width and short duration; author's comment] generates higher levels of welfare than does length protection because the period during which rivals can introduce applications of their own comes earlier and because the patentholder has more flexibility to decide when to exercise her property (patent) right".[16]

Application and Basic Technologies

The argumentation makes it clear that basic innovations have to be protected differently than application innovations to ensure lasting and successive scientific advancement for society. Basic knowledge of the construction and function of genes is of great importance for further achievement and innovation, especially in the genetic engineering sector. The DBP does not differentiate, however, between end products and basic genetic knowledge.[17]

Final products of genetic engineering are e.g. the anti-mush tomato, in which genetic information concerning ripening has been modified, or the IST corn seed produced by Novartis, which has an implanted resistance gene against certain insects, parasites and fungus. The basic technology on which these applications build is the knowledge of the genes used and of the proteins which code these genes. If the modified ripening gene could only be used in a tomato and if this gene had only this one simple function in the tomato, it would make no difference whether the tomato (as an application) or the gene (as the basic knowledge) was patented. In fact, however, genes are often involved in many processes in an organism and genes are applicable to many different organisms. Without going into further detail on these biotechnical considerations, one thing is clear: the decoding of a gene opens up a multitude of potential useful applications. Their realisation is dependent on the exclusivity (duration and width) of the property rights relating to the knowledge of the gene. By demanding completely the same protection for basic genetic engineering as for genetic products, the DBP does not take into account such circumstances and may even hinder research efforts rather than support innovation.

Unclear Definitions of Patent Width

The above discussion of optimal patent protection assumed implicitly that patent duration and width could be clearly defined ex ante by economic policy decision makers. While this could be applicable with

[13] A wide patent with a short term of validity is going to have less effect on basic discovery based advancement, while a narrow patent with a long term of validity, which promises the same benefit to the inventor, will cause enhanced advancement based on the basic discoveries.

[14] J. Lerner: The importance of patent scope: an empirical analysis, in: RAND Journal of Economics, Vol. 25, No. 2, 1994, pp. 319-333.

[15] But the maximum possible technical advancement, independent of whether it is a new idea or an incremental advancement of some initial idea or single innovation, is not necessarily also the optimal one. Rather, overinvestments can be caused, so innovation may be systematically introduced before the socially optimal point in time.

[16] C. Matutes, P. Regibeau, K. Rockett: Optimal patent design and the diffusion of innovations, in: The RAND Journal of Economics, Vol. 27, No. 1, 1996, pp. 60-83.

[17] Directive 98/44/EC, op. cit., Article 3, para. 1.

respect to the time variable, problems may emerge concerning the width variable when attempting to convert theoretical knowledge into daily practice. The length of a patent can be codified simply in laws, while the width emerges frequently as a figure based on subjective experience founded upon case decisions by the patent court, the task of which is to interpret this variable. Not only do inconsistencies exist between individual patent lawsuits, but changes in the width of patents are also noticeable over time. While e.g. US American courts guaranteed comparatively wide patents in the 1980s, since 1988 a clear reduction in the degree of protection could be registered.[18] The information provided by codified law and its implementation by the courts to the variable width are thus often incomplete in practice, so that frequently in individual cases a possible violation of exclusive rights must be judged to have taken place.

Such legislative and litigation procedures necessarily enhance social and private costs, which must not be overlooked in any evaluation of a patent system.[19] Furthermore, the distribution of these costs plays a decisive role for the achievement of R&D output in the area of existing patents. If an inventor has to expect high costs in the case of the courts proving a violation of a protection right, s/he will most probably stay away from this research area. The holder of a patent will most probably allow for innovations and imitation in her/his protected field, the higher the costs to her/him of enforcing her/his legal rights. The costs of the process of granting patents work in a similar manner. These costs are aggravated by the average time span of the institutional patent process, which for example is now roughly 2.3 years in Germany.[20]

Summarising, it can be argued that the application width of a patent cannot be precisely determined ex ante. This often results in long and expensive legal processes which increase the perception of uncertainty from the perspective of the patentee. Generally, this naturally has a negative effect upon the potential level of innovative activities. Even given the legal DBP regime, a rest element of uncertainty will always remain. Nonetheless, it may be argued that it is still conducive to the efficiency of the patent system if the underlying codified right contains as exact a definition as possible of what may be patented and how far the protection should go.

At present, the DBP is trying to reach this objective. However, within the current legal evaluation process, as well as in the recent evolution of the legal articles and paragraphs, and in the accumulated practical experience which could be collected to date, we can speak neither of an exact description of the extension of legal protection in the form of genetic patents nor of a clear definition of what exactly may be patented.

Large portions of the DBP (at least six of 18 articles) deal mainly with setting the boundaries of the legal protection of biological material and living organisms. Altogether three principal areas of great ethical importance are defined in which patents are not allowed to be granted: The human body and its elements, plant and animal varieties, and in the case of an offence against common public decency. All three areas having been defined and described, are then systematically qualified, so that in the final instance it does not seem credible to speak of a total patent ban. Where exactly the legislative body wishes the boundaries of patentability for living organisms to be remains unclear. Decisions by the European Patent Office confirm this. The DBP prohibits explicitly the patenting of plant and animal varieties, but allows for exceptions if the invention does not confine itself to only one particular variety. On 20 December 1999 the Enlarged Board of Appeal of the European Patent Office decided in the final instance that an invention can be patented given the inclusion of varieties.[21] The problem of distinguishing and drawing the boundary line is embedded in a complicated judicial line of argument which will not be examined in more detail here.

From the economic point of view, the fact is decisive that even legal experts specialising in biotechnology and European patent law find the differentiation between patentable animals and plants and non-patentable varieties difficult if not impossible. There remains much room for more transparency with regard to the legal statutes being implemented. On 21 February 2000 a press release revealed that the patent no. EP695351 granted in December 1999 is not in line with the DBP, as a biotechnological

[18] M. Plimier: Genentech, Inc. v. Novo Nordisk & University of California v. Eli Lilly And Co., in: Berkeley Technology Law Journal, Vol. 13, No. 1, 1998, pp. 149-161.

[19] M. Waterson: The Economics of Product Patents, in: The American Economic Review, Vol. 80, No. 4, 1990, pp. 860-869; G. Llobet: Patent Design under the Threat of Litigation, in: Asociacion Argentina De Economia Politica (ed.): The Twelfth World Congress Of The International Economic Association, Buenos Aires 1999 (CD Rom).

[20] H. D. Karl, L. Scholz, G. Wiesner: Biotechnologie - Abbau von Investitionshemmnissen im staatlichen Einflußbereich, in: ifo Schnelldienst, Vol. 42, No. 22, 1989, pp. 9-20.

[21] Bedeutung der Entscheidung der Großen Beschwerdekammer des Europäischen Patentamts vom 20.12.1999 im Fall Novartis, Pressemitteilung 7/99 des Europäischen Patentamtes, Munich 1999.

procedure was protected that could be theoretically used for the manipulation of embryonic cells of humans. Here the European Patent Office had to concede an error. This is a far cry from unambiguous definitions of protection width and the permissibility of patents.

This definition gap harms especially small and medium-sized enterprises (SMEs) which have been the innovation engine of this branch. Biotechnology and genetic engineering have been supported and advanced in their early years especially by small specialised firms. The following figures make this clear. In the USA 1300 biotechnology firms with some 120,000 employees existed in 1997. On average there where less than 100 persons employed in each firm. The founders were mostly young, entrepreneurial scientists from research institutes or universities.[22] Within the framework of the German Federal Research Ministry's "BioRegio" competition for the support of firm start-ups, 93 new enterprises emerged in 1996/97 in Germany. However, on average they created only 1 – 6 new jobs per start-up.[23] Still in 2000 only about one fifth of German biotechnology enterprises in the narrow sense (i.e. excluding equipment suppliers and subcontractors) employed more than 50 employees, and over 35 per cent of the companies employed a maximum of 10 people.[24]

Especially for SMEs, the often prohibitive costs of the patent system are a major reason for not patenting inventions. This holds particularly for SMEs in the biotechnological sector.[25] Patent rights disputes are commonly a decisive cause of those costs.[26]

Patent rights disputes are – as the above argumentation has shown – the result of inaccurate and incomplete definitions in the legal statutes. The economic incentives of the patent system are thus largely undermined and the desired positive effects of, for example, protecting young entrepreneurial innovative SMEs as major vehicles of scientific research achievements in the biotechnology sector fail to be achieved. The objective described in the first part of the DBP – the support of investment in biotechnology – is consequently only being realised to a very limited degree.

Conclusion

To be able to support and use the eminent chances of the European biotechnology sector efficiently, R&D departments of enterprises need clear patent policies, which on the one hand guarantee the legal protection of biogenetic technical inventions and at the same time make a wide access to genetic knowledge possible. Only thus would it be economically probable that the gene pool can ensure the development of a multitude of potentially commercially useful applications.

The DBP was originally conceived in order to clarify the various elements of uncertainty regarding possible claims to the legal patent protection of a biotechnology invention. Despite all of its legal practice phrasing this aim is missed. At the same time, there may be a negative effect on further innovation given that access to basic genetic knowledge is institutionally limited by patents. Global transnational corporations may be less affected by this situation. Their legal departments will probably understand how to interpret the existing inaccuracies to suit their needs in court. The losers are the small laboratories which have been the innovation engine of this still infant industry. Generally, SMEs in this technological area concentrate most of their resources on research and usually lack the means for judicial management departments. This problem is aggravated by the non-existing differentiation in the legal statutes between basic genetic inventions and genetic engineering innovations even though the basic genetic knowledge is of great importance to future advancement due to the distinctively sequential character of R&D in this area.

Characteristic of the non-optimality of the situation is the fact that the European Council has agreed to further discussions (in advance!) before the policy even comes into force. In Brussels, the German government has also advocated the "rethinking" of the DBP. Although biotechnology patent policy has been on the official European agenda for some 13 years now, the final clarifying act of the legislative process still remains a long, winding road. It remains to be seen how the European government will actually deal with the increasingly obvious inadequacies of directive 98/44/EC.

[22] G. Vita: Wachstumsindustrie Gen- und Biotechnologie. Life Sciences als internationale Zukunftschance, in: Internationale Politik, Vol. 53, No. 8, 1998, pp. 7-14.

[23] M. Kiper: Trendwende in der Gentechnik: Fiktion oder Realität? Zu den wirtschaftlichen und gesellschaftlichen Perspektiven der Gen- und Biotechnologie, in: WSI Mitteilungen, Vol. 51, No. 2, 1998, pp. 115-122.

[24] BioTechnologie – Das Jahr- und Adreßbuch 2001, Vol. 15, Berlin 2000, Biocom-Verlag.

[25] Europäisches Patentamt (ed.): Nutzung des Patentschutzes in Europa: Repräsentative Erhebung erstellt im Auftrag des Europäischen Patentamts; Schriftenreihe des Europäischen Patentamtes, Vol. 3, Munich 1994; H. D. Karl, L. Scholz, G. Wiesner, op. cit., p. 14.

[26] Official administrative patent costs also play a significant role in the calculations of SMEs, but these cost factors may at least be calculated in detail ex ante.