Commentary

The economics of biotechnology

Biotechnology may change the world. Given the chances and risks of this new technology, the key question from an economic point of view is whether incentives and regulation are appropriate. Both allocational and distributional effects turn out to be important.

Since James Watson and Francis Crick published their seminal paper on the structure of the DNA in *Nature* in 1953, research in genetics and its applications (biotechnology) has developed into an industry. Although genetics has triggered a revolution in our understanding in biology, implementation of biotechnology on an industrial scale is still rare. One might compare the current situation in biotechnology to the state of chemistry in the 1870s (Carr 2003). At that stage chemistry had just acquired a coherent theoretical framework, the periodic table. This theoretical framework was necessary to enable technology to change the production of well known products or even create a whole variety of new products (e.g. plastics) that were to become a part of our daily life.

Whether biotechnology will also develop into a mass industry which will eventually change our everyday life, is a question that still has to be answered. There is a huge potential. For convenience one uses colours to distinguish the applications of biotechnology: medical (red), agricultural (green) and industrial (white) applications. Medical applications include both the production of pharmaceuticals and genetic engineering. Some of the better known examples of medical applications are DNA sequences which are incorporated into bacteria or other other cells which are then used to produce proteins. Agricultural applications include transgenic plants whose genome has been modified by additional genes which allow them to be more resistant to weather conditions and insects, result in better yields, and still allow for less insecticides to be used. Some researchers attribute the largest potential to industrial applications with plastics and fuel as the two most promising examples.

Given the huge potential of biotechnology, the question arises whether the regulatory framework in place is appropriate to encourage research and applications in biotechnology. First, I describe the current regulatory regime. Second, I analyse its implications from an economic point of view. Green biotechnology is of particular importance for the developing world. I discuss economic aspects of its implementation. This essay concludes with a summary.

1. Regulatory framework

Intellectual property in biotechnology is ruled by patents. A patent provides a temporary monopoly to its owner to exclude others from using it. To obtain the patent, all information which is needed to replicate the underlying invention must be made public. An important aspect of a patent is that it is granted for a limited period of time, in most countries 20 years.

The rules according to which patents are granted rely on three simple and straightforward criteria (Rutz and Yeats 2004). In the following I refer to the Europen Patent Convention (EPC); similar regulations apply in the US, Japan and other countries. First, only inventions can be filed as patents. Discoveries, scientific theories, mathematical methods and aesthetic creations are specifically excluded from patentability (Art. 52 EPC). Second, the invention has to be considered to be new and not to form part of the state of the art (Art. 54 EPC). It has to include an inventive step (Art. 56 EPC). Third, there has to be an industrial application (Art. 57 EPC).

The most fundamental objection against patents in biotechnology, in particular with respect to genetic sequences and proteins, is that these are found in nature and therefore are mere discoveries rather than inventions. The discussion whether substances which can be found in nature might be

patented goes further back than the age of biotechnology. Before 1946 patent offices around the world would not patent natural substances. Only in 1946, the US patent office patented the antibiotic streptomycin to Merck. From that time on, the patent office took the view that whether a substance existed in nature or not, was not essential. Rather, the question to be addressed was whether a way was provided to isolate it and make it technically usable.

The criteria of novelty and inventiveness is used to establish a sufficient hurdle for an invention to obtain the status of a patent and its implied monopoly status. A patent on a human homologue of a mouse monokine was recently revoked as the two sequences overlapped to an extent of 80%[1].

The criteria of industrial application implies that the patent application has to be sufficiently specific. No patents will be granted if a sequence is identified, but no function is specified (such as ESTs 'expressed sequence tags'). The requirements are even stricter. For example, in general receptors with unknown ligands would not be patentable as an additional research program would have to be started to understand the physiological role of the receptor and hence allow for a technical usage of the invention. A current example is the patent withdrawal for the seven transmembrane receptor[2]. The underlying idea is that fundamental research should not be hampered by patent claims.

2. Economic aspects of the regulatory framework

In analysing a regulatory regime one has to consider two aspects: allocation and distribution. Allocation is the way resources are allocated for production; distribution is the way products are allocated for consumption. Both aspects are connected by the way how property rights are assigned.

Private companies are likely to pursue research wherever they expect attractive returns on their investments. If they perceive incentives not to be sufficient they will not invest. Therefore, the prospect of strong patent claims will encourage research. The downside is that once these patents are in place, the owners can exert monopoly power and exempt others from using the patent. This can lead to allocational effects which are not desired as other companies might restrain from investing in that area as they would not be allowed to make use of the patented technology, or would be allowed only at a preemptive cost. Moreover, this might lead to distributional effects which are undesired, because huge parts of the world population might not be able to afford medicine or agricultural products which rely on these patents.

Both concerns are warranted and have to be considered. The patent law does not provide for the rules of how a patent may be used. Additional rules and regulation are concerned with that aspect. In medical research, a company will want to obtain a patent before it embarks on costly clinical research. Clinical testing is required before a drug can be used and sold. The substantial cost incurred for clinical testing has to be matched by expected profits from the exclusive sale of the drug. To provide for this, commercial research using that patent without the consent of the patent holder is prevented by law. At first sight this may seem inefficient once the patent is available: the society would be better off if further commercial research would be possible at no additional cost for using the patent. Unfortunately, that setting is unavailable as the company investing into the research in order to obtain the patent has to rely on the promise that it will be able to use the patent exclusively.

Also, from a distributional aspect, the consequences of a patent to be granted might be unwanted. A company owning a patent on an AIDS vaccine can basically prevent major parts of the world from using it as prices might be set in a way such that the majority of the infected people would not be able to afford the vaccine. However, this is not only a question of the patent system but also of the rules for world trade.

There are at least two ways to deal with this problem. A conservative suggestion would be not to touch the way property rights are assigned, but to induce governments of developing countries,

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[1]Decision T 011/00 of the Boards of Appeal of the EPO, 14 February 2002, Monokine MIG induced by INF-GAMMA, http://legal.european-patent-office.org/dg3/biblio/t000111eu1.htm

[2]Decision T 1191/01 of the Opposition division 20 June 2001 – Novel Seven-Transmembrane Receptor V28, http://www.european-patent-office.org/epo/pubs/oj002/06_02

together with international aid organisations, to negotiate a price package with the patent holder for a particular drug to be delivered in a particular country at a lower cost. Such a solution might include an upfront fee to the patent holder. At the same time, the country would have to make sure that the drug does not get exported to countries where the drug is sold at higher prices. This suggestion would be comparatively easy to implement as it leaves property rights in place and is fully compatible with the current rules of world trade.

An alternative is to provide a mechanism at the WTO (or potentially at the WHO for green biotechnology) which would allow such an organization to influence the pricing of drugs in developing countries. This is a measure which interferes to a much larger degree with current rules of world trade and would have to be handled very carefully. If a certain illness does mainly prevail in a particular region of the world, this type of intervention is not advisable as it would subdue any further research into illnesses which are specific for that region of the world. Nevertheless, it might be a measure to accomodate distributional concerns in situations where illnesses are spread globally and the profit potential in the developed world might suffice to offset research costs which have been incurred (e.g. AIDS).

3. Green biotechnology in developing countries

Additional concerns might be raised related to green biotechnology. In most developing countries agriculture accounts for a large part of economic production and a majority of people earn their living from agriculture. Therefore, technological progress in agriculture is likely to have large effects in these countries.

Introducing transgenic plants into an ecosystem certainly has more than purely economic implications. The effects on the ecosystem, especially on native species, has to be evaluated and it has to be made sure that there are no unwanted side effects on the health of people once the plants are consumed. From an economic point of view, green biotechnology may have implications on agricultural production as it may change production methods and yields. From an allocational point these changes are most likely to be beneficial as they provide for a better use of the available resources.

The distributional aspects have to be evaluated case by case. One important aspect for economic policy is how a particular advance in biotechnology is likely to change the chances of small farmers relative to large agrofactories. It is difficult to make a general case that biotechnology will favour one or the other: in a recent study it turned out that Bt cotton provides for an increase in yields in particular when only small amounts of insecticides are available to farmers. If this is true, small farmers who tend to rely less on additional treatment for their production would benefit more from the introduction of Bt cotton than larger agrofactories (Qaim and Zilberman 2003).

4. Concluding remarks

The patent system provides for simple and effective incentives for research in biotechnology. Changes in the established system of intellectual property rights have to be handled with great care. Otherwise, private capital is likely to refrain from funding research in areas where it has to fear expropriation. Nevertheless, patents in biotechnology are not a means in themselves. In particular, developing countries will have to evaluate carefully the costs and benefits of biotechnology to be applied in their economies. In many cases, progress in biotechnology is likely to enhance welfare.

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MATHIAS KÜLPMANN,
HypoVereinsbank, Arabellastrasse 12,
D-81925 Munich, Germany
(Email, mathias.kuelpmann@hvb.de)

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