

Legal and social aspects of biotechnology in Poland*

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Legal and social aspects of biotechnology in Poland are of key interest for all of us but they are largely underestimated.

Biotechnology is a very broad notion and may be discussed in at least four different fields, quite often labelled by colours:

Green: this is agriculture and food industry; the commonly used name is agrobiotechnology.

Red: medicine, pharmacy and diagnostics are covered within this field.

White: industrial biotechnology.

Violet: legislation and socio-economic effects; this field of biotechnology can not be separated from the previous three because legal and social aspects are common for any application of modern biotechniques.

Biotechnology in Poland has different faces. These are science and technology, legislation and economy, and social aspects. Discussing the perspectives we have to take all of them into account. Polish biotechnology can be summarised as both "strengths" and "weaknesses":

STRENGTHS

- Polish legislation system (the most significant is "GMO Act"), (which covers European directives and Biosafety Protocol of Cartagena, Biodiversity Convention, TRIPs, intellectual property rights),

- high level of education in natural sciences,
- well educated young people with strong motivation,

- good logistics in academic cities (Warszawa, Poznań, Łódź, Gdańsk, Wrocław),

- market of 38 mln people,
- excellent geographical location.

WEAKNESSES

- general economic situation,
- poor industry,
- patents (including lack of knowledge of IPR),

- transfer of new technologies from academia to industry,

- industry-academia co-operation.

In the cases of green, red and white biotechnology, we usually talk exclusively in scientific and technical terms. However, the application depends on intellectual property rights, legal norms (domestic and international) and, last but not least, we need them in a supermarket who will buy the gene constructs, vectors, primers, etc. as standard consumer products (food, feed, energy, cosmetics, drugs, etc.). It is a common opinion of scientists that the real barriers for future development of biotechnology in the EU concern the "violet" biotech. How to solve the problem is the topic of many discussions during the scientific as well as diplomatic sessions. Europe has to be a "producer" of biotechnology goods and services not exclusively a "consumer".

The basic elements for future developments of biotechnology are: legal aspects of biotechnology, including intellectual property rights (IPR) and social aspects of biotechnology (including public perception) (Anioł & Twardowski, 2004).

The key elements of the Polish legislation are the following legal acts:

- 22.06.2001, *About GMO* (Dz. U. 25 July 2001, Nr 76, pos. 811). It is very important to note that on January 3, 2005, the Ministry of Environment presented for public discussion the project of a new Act "About GMO". This new project covers several new aspects including precautionary principle, labelling, coexistence of different agriculture

(ecoagriculture, traditional and biotechnology). For details see www.mos.gov.pl.

- 08.2001, *About Feed* (Dz. U. 25 October 2001, Nr 123, pos. 1350).

- 05.2001, *About Food* (Dz. U. 22 June 2001, Nr 63, pos. 634).

- 16 March, 2001, *About Ecoagriculture* (Dz. U. 22 June 2001, Nr 63 pos. 634).

- And the international acts incorporated in the Polish legal system: Directive 2001/18, Biosafety Protocol, etc.

The most significant is the act *About GMO* which covers the majority of aspects related to GMO:

- contained use,
- release to the environment,
- transportation and trade.

State of the art of biotechnology is focused on the assessment of national procedures, practices, policies and legislation concerning safe development and/or handling of biotechnology with the emphasis on measures to assess and regulate deliberate release of genetically modified organisms (Twardowski, 2003). It is very important to stress that Polish law is coherent with European regulations and international conventions, including the "precautionary principle" of *Biosafety Protocol* (Twardowski, 2003; Anioł & Twardowski, 2004). A separate issue of legislation is the protection of intellectual property rights (IPR).

The intellectual property rights in Poland are fully compatible with those of the European Union and the commonly used term "patent law" means exactly the same in legal terms (Twardowski & Twardowska, 2004). The most important legal act is the act of June 30, 2000, *On Industrial Property Law* and the amendment to the *Industrial Property Law* — June 2002, according to the Directive 98/44/WE (June 6, 1998) — on legal protection of biotechnological inventions, was enacted. The so called "new Polish patent law" includes modified regulations concerning the patentability of biotechnological inventions, and the last amendment (in force since October, 2002) of the *Industrial Property Law* harmonizes the Polish patent law with the EU Directive.

In order to illustrate the matter, the following examples of biotechnological inventions protected by patents are given:

- products: polypeptides (enzymes, antibodies), nucleic acids (primers, coding sequences, vectors, etc.), (micro)organisms, cell lines, kits (e.g., diagnostic kits), compositions (e.g., pharmaceuticals, vaccines);

- methods: production methods for obtaining products of interest (fermentations, methods for isolation and purification), assays and diagnostic methods *in vitro*, laboratory methods;

- uses: new application for already known product (second medical indication).

Patents often block the development of domestic technologies in Poland due to little knowledge of the regulations of intellectual property rights in academia. The transfer of new technologies from universities to the industry is limited, so is the direct industry–academia co-operation. Many patents will expire relatively soon and this will open a broad market for generic technologies. We can also expect "generics in fields other than pharmaceutical production, e.g., in agriculture.

The knowledge of the social aspects and particularly of the public acceptance of innovative biotechnology mostly comes from surveys of public opinion (Twardowski *et al.*, 2003). We have analysed public perception of biotech several times in recent years, analysing the following:

- common opinions *versus* scientific facts,
- public acceptance of novelty,
- diversity of educational background (including religion, philosophy and ethics).

The most important conclusion is a very bitter one: biotechnology, biotechnologists and biotech products have lost 40% of trust for the last 5 years. In contrast, the general knowledge of biotechnology in Poland is much higher than in other countries. The barriers to public understanding and acceptance of biotechnology are several; as a consequence the transfer of knowledge from the "temple of science" to lay people is extremely difficult and highly limited. In our interpretation the key factor is understanding of novel technology.

The limitations for the future development (Twardowski *et al.*, 2003; Twardowski & Bielecki, 2004) of Polish biotechnology are numerous:

- too few science parks and incubators,
- limited number of centers of technology transfer,
- insufficient information flow between industry and academia,
- universities are poorly oriented to the needs of the market,
- industry is not familiar with the innovation potential of university research,
- scientists and institutes are ranked mainly according to the number of publications and not for applied research and cooperation with industry.

In conclusion, we may formulate the needs of biotechnology commercialisation. However, we should take into account the specificity of biotech industry characterised by: long terms, high riskiness investments, international markets. Because of that, we need:

- regulations,
- intellectual property rights protection,
- technology transfer.

A definition of the strategic aims in Poland is urgently needed regarding high-tech, like biotechnology. The next step should be building the platforms

for closer contact between industry and academia and investment in science parks especially from the structural funds of the EU. We should hope these will help us to develop a strong national biotechnology industry.

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