

Biopatent Law: Patent Strategies and Patent Management

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General Issues of Biotech Patents

Andreas Hübel

Abstract Biotechnological inventions are clearly patentable when meeting the requirements set by the patent law. These requirements are based on well-established requirements. However, unique requirements were established such that the peculiarities of biotechnological inventions can be considered. Nonetheless, it appears that certain specific regulations for obtaining patent protection for a biotechnological invention poses more burden to an applicant than seeking patent protection in other disciplines.

Keywords Biotech · IP · Patents · Patentability · Invention · Novelty

1 Introduction

Humans have been using microorganisms and their metabolic products for centuries, for example when preparing food such as bread made of sour dough, cheese, wine, or other alcoholic beverages. However, it was only discovered in the mid nineteenth century that living microorganisms were responsible for such processes, and subsequently individual strains of microbes were isolated for further use. Besides, biology was a rather descriptive discipline sharing little with chemistry, physics, or engineering. Experimental biology such as the research conducted by Gregor Mendel (1822–1884) concerning genetic inheritance appeared to be an exception rather than the common approach. However, upon

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elucidating the double helix structure of DNA, characterizing the basic principles of how genetic information is passed and realized, i.e. the genetic code and messenger RNA, and identifying restriction endonucleases biological science evolved to a technical discipline nowadays called biotechnology.

Today, there is no doubt that molecular biology, molecular genetics, and biotechnology are disciplines that provide technical improvements and solutions for technical problems. Hence, the results provided by these disciplines are vulnerable to patent protection such that the inventors can commercialize their finding under a limited exclusivity. The latter appears to be particularly appropriate because bringing a biotechnological invention into the market is often a very developmentally intense project.

Patents are recognized as means for protecting intellectual property and inventions. Patents provide exclusivity for the inventor in commercializing his invention. By granting a patent, a state cedes some of its rights to the patentee. To allow a patentee to enforce the right that was ceded to him, the patent has to meet various criteria that are examined before the patent right can in fact be granted to the patentee. Over time those criteria became well established for technical disciplines and evolved along with the technical progress in the technical disciplines. Of course, these criteria were and have to be applied to biotechnological inventions as well. However, it turned out that some of the criteria were insufficient for appropriately protecting biotechnological inventions due to the peculiarities of this discipline. Hence, the criteria were amended, common criteria were interpreted in new ways when applied to biotechnological inventions, and new criteria were set up. Moreover, the intellectual property right for biotechnological inventions is still changing as ever new issues arise in this fairly young subject.

This chapter will illustrate and discuss the general issues of patenting biotechnological inventions, and emphasize the peculiarities in this regard. A focus is set on European patent regulations, but differences in other jurisdictions are mentioned if considered necessary by the author. All the decisions identified in this chapter can be accessed online via the database of the technical board decisions of the European Patent Office (EPO).¹

2 General Principles

Patent law developed criteria for assessing whether an invention is patentable or not. These criteria are applied to biotechnological inventions too. These criteria are discussed and illustrated with respect to biotechnological inventions herein below.

¹ Available online under http://www.epo.org/law-practice/case-law-appeals/search_de.html.

2.1 *Discovery Versus Invention*

Patents shall be granted to inventions provided they are new, involve an inventive step, and are susceptible to industrial applicability. This is what basically every patent law in the world provides by one wording or another. Surprisingly, no patent law comprises a clear and unequivocal definition of what an invention in fact is. One has to rely on case law to figure out what—at least the German Supreme Court in the case “Rote Taube”²—regards as an invention. The red dove is a new species of doves resulting from crossing and selective breeding of already existing species. Although genetic crosses are biological processes, human selection is a technical aspect. Hence, the German Supreme Court concluded that a selective and systematic exploitation of natural forces including biological forces should not be excluded from patent protection.

The patent laws themselves do not define “invention”. The patent laws may define what shall not be regarded as an invention. The EPC for example defines that discoveries, scientific theories, mathematical methods, aesthetic creations, schemes, rules and methods for performing mental acts, playing games or doing business, programs for computers, and presentation of information shall not be regarded an invention.³ Hence, no European patent can be obtained for any of the said subjects. For example, it is a discovery if a natural ligand for a given receptor is identified. Hence, the binding of the ligand to the receptor is not patentable. However, a medicament comprising the ligand for treating a specific disease is patentable.

In addition, it is provided that European patents shall not be granted for inventions, the commercial exploitation of which would be contrary to “ordre public” or morality, plants, or animal varieties, essentially biological processes for the production of plants or animals, and methods for treating the human or animal body by surgery or therapy, as well as diagnostic methods practiced on the human or animal body.⁴ One such example are human embryonic stem cells which require destruction of a blastocyst which in turn is considered as “human embryo.”⁵

2.2 *Novelty*

For an invention to be patentable, it has to be novel. To be novel in the meaning of patent laws means that the invention shall not have been disclosed in any way prior to the first filing of the application for a patent. The invention shall not form part of the state of the art, i.e. the knowledge to mankind. State of the art in turn is everything made available to the public before the date of filing the patent

² GRUR 1969, 672.

³ Article 52(1) EPC.

⁴ Article 53 EPC.

⁵ Decision G 2/06 of Enlarged Board of Appeals of EPA, Decision of ECJ in case C-34/10.