

# Patentability Requirements of Biotech Patents

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**Abstract** This chapter discusses patentability requirements in the two major patent jurisdictions, namely novelty, non-obviousness/inventive step, enablement/written description, best mode, and sufficiency of disclosure. Differences between Europe and the United States are highlighted, and practical implications are discussed with respect to the biopatent field.

**Keywords** Novelty • Obviousness • Enablement • Written description • Best mode • Industrial applicability • Inventive step • Sufficiency of disclosure • Biotech

## 1 Introduction

As discussed earlier in this book series, the allowance of a patent is subject to substantial examination. During this process, a number of tests is carried out, part of which are similar in the major patent jurisdictions, while others differ from one another substantially.

In the US patent system, the United States Code, Section 35 (USC 35) is decisive, whereas in the European patent system, the European Patent Convention (EPC) sets the standards. The following list gives an overview of the patentability requirements under USC 35 and EPC.

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| USC 35                          |             | EPC                                                                          |                      |
|---------------------------------|-------------|------------------------------------------------------------------------------|----------------------|
| Requirement                     | Legal basis | Requirement                                                                  | Legal basis          |
| Novelty                         | § 102       | Novelty                                                                      | Art. 54              |
| Non-obviousness                 | § 103       | Inventive step                                                               | Art. 56              |
| Enablement requirement          | § 112       | Sufficiency of disclosure                                                    | Art. 83              |
| Written description requirement | § 112       |                                                                              |                      |
| Best mode                       | § 112       | Industrial applicability and exclusion of methods of treatment and diagnosis | Art. 57, Art. 53 (c) |

The present chapter will focus on a comparison of the tests as to novelty as carried out by the USPTO and the EPO to patents from the biotechnology discipline. Before doing so, however, some requirements specific to the two jurisdictions will be shortly addressed.

## 2 Foreplay: Requirements Specific to Either the EPC or USC 35

### 2.1 *Industrial Application (Art. 57 EPC) and Exclusion of Methods of Treatment and Diagnosis (Art. 53 (c) EPC)*

The test on industrial application as applied under Art. 57 EPC was initially used to block inventions which were related to therapeutic and diagnostic methods. The ratio behind this ban is that medical practitioners should not care about patents when deciding about practicing a given method of therapy or diagnosis. The industrial application standard is derived from the fact that, in Europe, medical professions are not considered to qualify as “industrial” or commercial. The exclusion of methods of treatment and diagnosis of humans and animals is furthermore specifically codified in Art. 53 (c) EPC.

#### 2.1.1 Compound Patents Which Suffer from Insufficient Disclosure

Recently, Art. 57 has been used to block therapeutic compound patents which were filed at a stage where the applicant had no idea of the potential therapeutic use yet. Decision T870/04, which related to a patent application encompassing the hematopoietic cytokine receptor, and therapeutic antibodies binding thereto set forth that

the mere fact that a substance can be made in some way does not necessarily mean that Art. 57 EPC is fulfilled, unless there is also some profitable use for which the substance can be employed.

However, this bar is very low. Technical Board's decision T0018/09 made this clear. The underlying patent EP0939804 assigned to HGS related to nucleic acids encoding for Neutrokin- $\alpha$  and an antibody that binds specifically to Neutrokin- $\alpha$  (now: BLyS or BAFF). Neutrokin- $\alpha$  is a member of the TNF- $\alpha$  superfamily, and was novel at the time of filing, but no experimental data were given as to therapeutic use, nor was a real antibody made. The applicant had only provided tissue distribution experiments of Neutrokin- $\alpha$  mRNA).

Nonetheless, the board judged that tissue distribution data suffice for industrial application and may be used to develop appropriate means for diagnosis and treatment. The key statement reflecting the board's opinion was as follows:

In the board's judgment, the tissue distribution of Neutrokin- $\alpha$  mRNA disclosed in the patent-in-suit, in particular the expression of Neutrokin- $\alpha$  mRNA in B cell and T-cell lymphomas (...), provides in itself in the context of the disclosure a valid basis for an industrial application. The presence of Neutrokin- $\alpha$  in these lymphomas 8...] may be used to develop appropriate means and methods for their diagnosis and treatment based on the disclosure of the patent-in-suit.

The patent was thus maintained.

In corresponding proceedings in the UK, the Court of Appeal found the patent invalid for lack of industrial applicability, insufficiency, and obviousness, but the Supreme Court overturned this view, re-established industrial application and remanded the case. The Court of Appeal then established validity on September 5, 2012.

This decision thus defines the bottom line of real-world evidence applicants need today to meet the industrial application requirement in case they want to protect a new therapeutic compound. It is thus fair to say that, in today's examination policy, the industrial application requirement is easily met and has a practical role only when it comes to methods of treatment and diagnosis.

## 2.1.2 Medical Use Claims

Inventions that relate to a new indication for a pharmaceutical drug suffer from a conceptual problem, because, on paper, they relate to the use of said drug for a medical purpose and, as such, to a method of treatment which is exempt from patent protection under Art. 53 (c) EPC.

Under the last version of the EPC ("EPC 1973"), so-called Swiss-type claims were the only acceptable form of claiming a second medical use, because only under this wording an exclusion under then Art. 52 (4) EPC (now Art. 53 (c)) could be avoided. The Swiss-type claim language, which claimed the "Use of compound X in the manufacture of medicament Y for treatment of disease Z," was established by the Enlarged Board of Appeal (EBA) of the EPO in decision G5/83.

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