

Stockholm May 22 2026

Subject: Input on EPO Guidelines G-II, 6.2 – Inventive step of antibodies

Dear Sir/Madam,

The industry association SwedenBIO works to promote a competitive life science sector in Sweden. We do this by facilitating effective networking between different industry players, building knowledge, and giving the sector a strong voice in public debate. Our 330+ member companies are active in pharmaceutical development, biotechnology, medical technology, and diagnostics, or are experts in areas such as business development, financing, intellectual property, and legal affairs.

SwedenBIO appreciates the opportunity to provide input on the 2026 revision of the EPO Guidelines for Examination, in particular Part G-II, 6.2 on the assessment of inventive step for antibodies.

Sweden has a strong and research-driven life science sector, where antibody-based innovations play a vital role in developing new treatments for serious diseases. A well-functioning and predictable patent system is essential to enable long-term investment, foster innovation, and ultimately ensure that patients gain access to new therapies.

Against this background, we would like to share the following perspectives.

A need to avoid assumptions of obviousness

We acknowledge the adjustment to the introductory wording of the Guidelines as a constructive step. However, the current text still reflects an underlying assumption that antibodies developed using known techniques are generally obvious.

In our view, this does not fully reflect the realities of antibody research and development. The development of functional antibodies is a complex and iterative process, involving numerous technical choices and uncertainties. Outcomes are often difficult to predict, even when established methods are used.

Branschorganisationen SwedenBIO arbetar för en konkurrenskraftig life science-industri i Sverige. Vi gör det genom att skapa effektiva kontaktytor mellan sektorns olika aktörer, genom att bygga kunskap och genom att ge branschen en stark röst i samhällsdebatten.

It is therefore important that inventive step continues to be assessed on a case-by-case basis, without general presumptions applying to a specific field of technology.

Ensuring a balanced and technology-neutral framework

The current Guidelines outline a limited set of ways in which inventive step can be demonstrated while discouraging certain types of arguments, particularly those relating to structural features and sequence-based unpredictability.

From an industry perspective, this creates an unnecessarily narrow framework. Patentability criteria should be applied in a consistent and technology-neutral manner across different fields. Introducing specific limitations for one class of inventions risks creating uncertainty and diverging standards.

A broader and more flexible approach would better reflect the diversity of innovation pathways in antibody development.

Alignment with established principles and practice

We note that the current approach appears to diverge from how structurally defined inventions are assessed in other areas, including small-molecule chemistry.

Antibodies are, at their core, defined by their amino acid sequences, and their functional properties are closely linked to these structures. Consideration of structural differences and their impact on function is therefore highly relevant when assessing inventive step.

Ensuring that similar principles are applied across technologies would improve coherence and predictability for applicants.

Supporting Europe's innovation environment

The way inventive step is assessed has implications beyond individual patent applications. A restrictive or uncertain framework can affect investment decisions, collaboration opportunities, and the willingness to pursue high-risk research projects.

This is particularly relevant for small and medium-sized enterprises, which are key drivers of innovation in the biotechnology sector. A predictable and proportionate approach to patentability is essential to maintain Europe's attractiveness as a location for life science research and development.

Ultimately, this also has implications for patients, as it influences the pace at which new therapies are developed.

Branschorganisationen SwedenBIO arbetar för en konkurrenskraftig life science-industri i Sverige. Vi gör det genom att skapa effektiva kontaktytor mellan sektorns olika aktörer, genom att bygga kunskap och genom att ge branschen en stark röst i samhällsdebatten.

Proposed way forward

In light of the above, we would encourage the EPO to consider the following:

- Avoid any explicit or implicit presumption that antibody inventions are inherently obvious;
- Ensure that examination practices do not rely on general assumptions that outcomes derived from known techniques are routine or predictable;
- Allow full consideration of relevant scientific arguments, including those based on structural characteristics and structure–function relationships;
- Strive for consistency in the application of inventive step across different fields of technology.

More broadly, we question whether a dedicated section for antibodies is necessary, as a common framework based on general EPC principles would support greater consistency and clarity.

We appreciate the EPO's continued dialogue with stakeholders and its efforts to maintain a high-quality and balanced patent system in Europe. We hope these comments can contribute constructively to that work.

Yours sincerely,



Jessica Martinsson

CEO, SwedenBIO