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The approach to the assessment of inventive step of antibodies at the EPO – is there an artificial barrier and should it be broken?

Brian Cordery (Bristows) · Thursday, March 27th, 2025

On 9 January 2025 I reported on Parts 1 and 2 of a three-part article in **EPI Information** by **Tamaris Bucher**, a Principal Patent Attorney at Novartis Pharma AG, on the current approach to antibody patents at the EPO. In Parts 1 and 2, Bucher argued that Part G.II.6.2 of the EPO Guidelines, which starts with a presumption that antibodies are *prima facie* non-inventive, creates an artificial barrier to obtaining patent protection for antibody inventions and sets a higher standard for the assessment of antibody claims that does not have clear basis in Art. 56 EPC or EPO case law.

Bucher's submission in Part 3 of the article is that the EPO Guidelines on inventive step for antibody patents are based on an unfounded prejudice that antibody generation work is routine and do not reflect the fact that antibody development and engineering for diagnostic or therapeutic purposes is a highly complex art requiring inventive skill. Scientists do not simply vaccinate an animal with the target and apply the product of the Köhler-Milstein hybridoma technique in a diagnostic or therapeutic context. Rather, the development of commercially relevant antibodies follows an unpredictable path and involves the combination of multiple techniques with the goal of obtaining an antibody with appropriate affinity, biological activity, selectivity, cross-reactivity, immunogenicity, stability, solubility, viscosity, aggregation, purity and biophysical criteria and the absence of undesirable post-translational modifications. Therapeutic and diagnostic antibodies are not simply products of nature, as the EPO appears to view them.

Part 3 presents a proposed solution. The starting point, according to Bucher, is to bring the Guidelines on antibodies into consistency with the principles applied to small molecule compounds and to step back from the use of the term "antibody" in the formulation of the objective technical problem. Typically, the objective technical problem for antibody claims is formulated as (i) *the provision of an antibody to the target X that exhibits the relevant improvement* (where there is an improvement in a particular property) or (ii) *the provision of an alternative antibody to the target* or *for use in the same purpose* (where no improvement is identified). However, in Bucher's view the use of the term "antibody" may have the inadvertent effect of causing EPO examiners to overlook the variability in antibody complementarity-determining regions (CDRs, the regions of antibodies that are responsible for binding to the target). Unlike small molecule compounds, for which structures are claimed as graphical representations, antibodies are represented by seemingly generic terms ("SEQ ID No. Z" or "SEQ ID No. ZZ", which each represent a series of amino

acids) so differences between 3D structures are less apparent. This makes it easier for examiners to overlook the different structures in the paratope (the part of the antibody involved in binding to the target) in claims defined by specific CDR or VH/VL sequences. The issue is further compounded by the discouragement of the assessment of structural information in Part G.II.6.2 of the Guidelines.

Bucher suggests reformulating the objective technical problem as *the provision of a specific alternative molecular structure (or sequence) for use in achieving the functional activity Y* to reflect the complex and varying structures that can be represented by sequences in different SEQ IDs. For the final step of the problem-solution approach – in which it is considered whether or not the claimed solution, starting from the closest prior art and in light of the objective technical problem, would have been obvious to the skilled person – Bucher argues that the correct question should be whether the claimed antibody with its specific amino acid sequences **would** have been made by the skilled person by following the prior art and with a reasonable expectation of success of achieving the desired activity, not whether it **could** have been made using unlimited time and resources.

The key question that arises is what the impact would be of such a change of approach in relation to antibody claims. Bucher argues that it would be limited: claims to antibodies defined by SEQ ID are relatively narrow in scope so the grant of additional antibody patents would not be problematic for the antibody field or detrimental to the public in general. Whether readers agree or not it is clear that this is an area ripe for consideration given the importance of biologics in modern healthcare. Bucher's article series has already generated significant discussion amongst patent practitioners so there is clearly momentum for further debate – and potentially a change in approach – in this critical area.

Ms Bucher's article can be found at the following link:

epi Information | The Barrier Around Antibody Inventions at the European Patent Office

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