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The Approach to the Assessment of Inventive Step of Antibodies at the EPO – a Critical Analysis

Brian Cordery (Bristows) · Thursday, January 9th, 2025

The festive period normally leads to a slight slow-down in work in Europe and as such, it can provide the opportunity to catch up on wider reading as well as to grab a little rest. In between the years 2024/5, I read Parts 1 and 2 of an interesting three-part article in **EPI Information** by **Tamaris Bucher**, a Principal Patent Attorney at Novartis Pharma AG, on the issue of the granting of patents to antibody inventions at the EPO. Ms Bucher, who possesses over 20 years of experience in practice as a patent attorney, takes issue with the EPO Guidelines concerning the assessment of the inventive step for claims to new antibodies and argues that they are inconsistent with the EPO's approach to inventive step in other areas, such as those for small molecules in which predictability of the structure-activity is considered. Part 3 – to be published early in 2025 – will provide a proposal solution to the issue.

Following a brief introduction, Part 1 of Bucher's article points the spotlight directly on Part G.II.6.2 of the EPO Guidelines (2024 version) ("the Guidelines") which state: "*The subject-matter of a claim defining a novel antibody binding to a known antigen does not involve an inventive step unless a surprising technical effect is shown in the application or unless there was no reasonable expectation of success of obtaining antibodies having the required properties (cf G-VII, 13). Examples of surprising technical effects include an unexpected improvement over prior-art antibodies in one or more properties, such as therapeutic activity, stability or immunogenicity, or an unexpected property not exhibited by prior-art antibodies.*" Further, at the end of the Guidelines, two further exceptions are identified which could permit the recognition of an inventive step: "*Nevertheless, antibodies can be inventive if the application overcomes technical difficulties in generating or manufacturing the claimed antibodies. A novel type of functional antibody format may also be considered inventive.*"

As Bucher observes, the general wording of the Guidelines is both negative and unequivocal ("*does not*") and seems to go against Art 56 EPC itself which does not contain such a presumption. Bucher considers the explanations given by the EPO for their Guidelines but is not convinced by them as she explains in her detailed analysis of the case-law cited by the EPO.

Part 2 of Bucher's article drills down into two of the exceptions (cited above) which are prescribed by the Guidelines to the premise that a novel antibody binding to a known antigen is prima facie obvious, namely: (i) a surprising technical effect; and (ii) a claim to a novel type of functional antibody format. In relation to (i), among other things, Bucher revisits the TBA decision in T645/02 – which was the original antibody case upon which the later cases cited in the Guidelines

rely upon as authority for the proposition that a surprising technical effect is required – and concludes, from an analysis of the original German text, as well as the English translation, that this decision did not refer to a "surprising technical effect" but rather that the provision of a particular antibody with certain precisely defined properties had the elements of surprise, rather than the surprising technical effect per se being surprising. She posits that what was being recognised was the non-obviousness of the manner in which that improved technical effect was achieved i.e. essentially the unpredictability in the structure-activity relationship. As regards the second exception, namely a novel type of functional antibody format, Bucher notes that this permits EPO Examiners to consider at a high level of resolution the structural configuration of a claimed antibody against the prior art. However, the particular amino acid sequences, for instance within a variable region, are discouraged from being taken into account. The devil – or should it be the angel? – is often in the detailed information and when it comes to the functionality of antibodies, Bucher finds that the approach in the Guidelines discouraging the assessment of the predictability of detailed amino acid sequence information is "*simply not justified*".

I'm looking forward to reviewing Part 3 of the article which, as noted above, promises to outline a new proposal for the formulation of the objective technical problem for antibody inventions. Although I am a patent litigation lawyer and hence not involved directly day-to-day in the prosecution of patent applications at the EPO, it seems to me that this is an important issue worthy of wider consideration.

Ms Bucher's article can be found on the following link: epi Information | The Barrier Around Antibody Inventions at the European Patent Office

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