Patenting research outputs – sufficiency in different jurisdictions

As we continue our series on considerations for researchers interested in patenting their research outputs, WP Thompson looks at the requirements of different jurisdictions to identify how much detail is needed in a patent application for it to be held as sufficiently disclosing an invented product.

Sufficiency of disclosure

Patent applications in the chemical and biotechnology sectors often describe inventions in detail. They can also include large numbers of examples and data to help show that an invention works and to describe the features and interactions therebetween in specific workings of that invention. These data are intended to disclose to the skilled person in sufficient detail how to work the invention.

Based on common filing strategies, inventors/applicants typically look to satisfy the requirements at the European Patent Office (EPO), the UK Intellectual Property Office (UKIPO) and the US Patent and Trademark Office (USPTO). However, the judicial framework within which each office needs to work results in relatively closely aligned offices, such as the UKIPO and EPO, having different approaches to assessing sufficiency. Three decisions issued this year have highlighted these differences, which must be borne in mind when applicants provide data and embodiments to support their patent applications.

The European approach

A recent decision issued by the EPO's Board of Appeal (T 0835/21) regards a patent for antibodies, or antigen-binding fragments thereof, that bind to the human low-density-lipoprotein receptor-related protein 6 polypeptide (LRP6), and their use in the treatment of cancer. An opponent of the patent alleged that the number of compounds that would need to be tested to arrive at the claimed antibodies, in the absence of a reproducible example, would demand an unreasonable amount of trial-and-error. However, the Board of Appeal decided that the tools for identifying antibodies with the claimed characteristics were well-known and that the application would successfully lead the skilled person to the invention since they could readily identify failures. The invention was thus deemed sufficiently disclosed simply because the skilled person would be able to make the antibodies in question.

The US approach

In the US, *Amgen Inc. v Sanofi (No. 21-757)* considered a pair of patents also claiming antibodies; specifically, an entire genus of antibodies that bind to specific amino acid residues on the protein PCSK9, or block PCSK9 from binding receptors responsible to extract low-density lipoprotein cholesterol from the bloodstream. Despite providing amino acid sequences of twenty-six suitable antibodies and methods for making other suitable antibodies, the patents were held to cover far more than those twenty-six antibodies, thus encompassing more than the skilled person was taught how to produce. It therefore appears that applications in the US might require at least one example that demonstrates a common quality of the members of a claimed class, in order to be considered sufficient, in contrast with the European approach.

The UK Approach

The UK approach to sufficiency involves the additional requirement of plausibility. *Sandoz v BMS ([2023] EWCA Civ 472)* concerned a patent disclosing lactam-containing compounds and derivatives thereof as Factor Xa inhibitors, which are used to treat thromboembolic disorders. The first claim to the invention related to such a use of the individual compound apixaban. However, the application was said to do no more than assert that apixaban could be used as such an inhibitor, without plausibly demonstrating the truth of this assertion. Without a plausible, and thus sufficient, use the patent was considered to be directed to the compound itself, the mere identification of which is not inventive. Although it concerned a claim to a single compound, rather than a group thereof, this decision demonstrates that supporting data can play an important role in seeing a patent granted in the UK.

Thinking ahead

The UK and US decisions discussed above cite the notion of the *"patent bargain"*, wherein an inventor receives a monopoly right for their invention in return for disclosing it for the public to use after the right expires. Whilst the EPO appears to take a less stringent approach to how sufficient this disclosure must be, inventors should always bear in mind this purpose of a patent, as well as considering in which jurisdictions protection might be of interest, when deciding if they have enough supporting data to proceed with filing their patent application.

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