the expense of differentiation and could act as a switch between cellular states. However, what is not clear from the current study is which of these functions of AP2γ is most pertinent to the aetiology of breast cancer. As ectopic expression of AP2γ was not sufficient to induce mammary tumours in the transgenic mice, it is unlikely that AP2γ initiates breast cancer. Instead, a role in tumour progression is more probable. This transgenic model will doubtless prove a valuable tool with which to further dissect the role of AP2γ in this complex process.

9 Jager, R. *et al.* (2003) Transcription factor AP2γ stimulates proliferation and apoptosis and impairs differentiation in a transgenic model. *Mol. Cancer Res.* 1, 921–929

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Business

Patents

'Tense' matters in patent applications

The recent opinion issued by the Court in the Hoffmann-La Roche (http://www.roche.com) versus Promega (http://www.promega.com) case is an eye-opener to the handling of patent examples in patent applications [1]. In the case referred, Roche had a prophetic example (experiment that was not performed) written in past tense. The court held that drafting an example in past tense, when it has not been performed, misleads the reader and thus amounts to inequitable conduct. In some circumstances, inequitable conduct is adequate to invalidate a patent.

Patent applications should minimally consist of a specification including the title, abstract summary and illustrations, if necessary, and at least one claim. Patent examples are drafted as a part of the specification and often aid in describing given experimental data associated with the invention. The patent example section is not an absolute requirement for filing an application. However, for biotechnology applications, it has been useful in rendering use and enablement support for the claimed invention. As far as the language goes, patent examples are described in the past tense while describing the experiments performed. It is often a practice in the patent world to describe the experiments 'to be done' under patent examples. These examples are written in the present or the future tense and are called as prophetic or paper examples. Describing the prophetic example(s) in the original application helps later in the prosecution to introduce the data in the form of a declaration.

The art of writing patent applications is constantly evolving. However, there are guidelines that are given in the Manual of Patent Examining Procedure (MPEP) that the patent examiners refer to. MPEP clearly states how the examples should be drafted in a patent application. The lesson learnt here is that caution needs to be exerted when describing prophetic examples. The authors give some helpful hints on how scientists and practitioners can make a concerted effort in order to avoid such mistakes.

1 Potter, J.E. and Talukder, G. (2003) Past versus present: the importance of tense in patent application examples. *Nat. Biotechnol.* 21, 1397–1398

What next for research tool patents?

Often, landmark discoveries related to drug candidates make big news, however, lost in the glory of the new drugs are the research tools that are used in discovering the drug targets [2]. If patented, these tools are important sources of revenue for academia and biotechnology companies.

However, research tool patents have been a challenge to enforce. This is partly due to the 'research exemption' rule detailed in Section 271 (e) (1) of Title 35 of the United States Code (USC), which enables the generic drug makers to get regulatory approval before the drug patent expired. However, the breadth and scope of 'research exemption' rule has served as a 'safe harbour' for many drug discovery efforts, making it difficult for research tool patent holders to prove infringement.

Raubicheck *et al.* [x] review the renewed value of research tool patents in the wake of the Integra versus Merck decision. The Integra (http://www.integra-ls.com) patent claims compositions and method relating to an RGD peptide that regulates cell adhesion. Scientists from the Scripps Research Institute (http://www.scripps.edu) under a license agreement with Merck (http://www.merck.com) used the patented peptide for identifying novel antiangiogenic drug candidates; Integra argued that Merck infringed the peptide patents by using the claimed peptides. Merck defended that the drug-screening activities were exempt from liability for infringement under USC 271 (e) (1), because they were 'reasonably related to' information required by the FDA. The Court ruled that the use of the patented peptide in the early stage drug-screening activity does not directly lead to clinical testing required by FDA and thus can not be sheltered under research exemption.

Although more clarity is required in terms of defining exemption, the Integra decision partially salvages the 'value and glory' of research tool patents. However, on the issue of 'value', damage analysis and reasonable royalty estimates could be particularly problematic for research tool patents, which by themselves might have no market value. Thus, it might be prudent for patent owners or research tool users to consider the 'value' of the patented tool carefully before considering litigation or licensing.

1 Raubicheck, C. *et al.* (2003) Integra versus Merck: a mixed bag for research tool patents. *Nat. Biotechnol.* 21, 1099–1101

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