

## PATENT PRIMER

## Grace periods and patentability

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Recent patent case law has indicated that there is a trend for more experimental support in patent applications. However, having to publish such research could delay filing and undermine the novelty of the invention, whereas not publishing the work in a competitive research environment could allow other groups to publish first. This article highlights differences between the provisions in patent law in different countries that facilitate these seemingly conflicting requirements.

**Filing versus prior disclosure**

Recent case law has demonstrated a requirement for substantial experimental support in a patent application in cases in which ‘proof’ of the invention is required. Such reasoning is exemplified by the Mycogen decision (see BOX), which sums up the current thinking regarding the requirement for experimental support in an application.

In practical terms, the desired effect of this requirement is to delay filing a patent application until that application is supported by at least some experimental data. This is most often the case when an ‘invention’ relates to a commercial application (‘industrially applicable’) or the development of results from basic research. Furthermore, the experimental support in an application should relate directly to the ‘invention’ and not the basic research underlying the hypothesis that led to the invention. That is, if an invention relates to the use of a substance in the discovery or development of a drug to treat a defined disease, the experimental support relating to the therapeutic treatment of that disease must be provided in the application; it is not sufficient to provide the results of basic research that only indicate a possible correlation of that substance with a disease.

Because published academic research often describes the results of basic research rather than research applied to drug discovery, and because the competitive nature of research dictates the early publication of such data, using this type of experimental support is often either not appropriate or could potentially destroy the novelty and inventive step of a later patent application describing an industrially relevant application of this basic research. To try to address this conflict between the

requirement for disclosing experimental data and the caveats in doing so, several countries have incorporated ‘grace periods’ into their patent legislation.

**Periods of grace**

In the US, a grace period exists that enables an inventor to publish experimental data supporting the invention before the filing date without jeopardizing the validity of the patent application, provided that the filing is made within 12 months of publication. In effect this means that an inventor is free to publish his basic research without the concern that such a publication will prohibit obtaining a patent for that subject matter during the following year. Similar legislation is effective in other countries; for example, in Japan there exists a 6-month grace period and in Canada a 12-month grace period, and similar provisions are made in Argentina, Belarus, Brazil, Republic of Korea, Mexico, Russian Federation, Ukraine and Turkey. This is in contrast to European patent law, which provides little help in overcoming the effects of a disclosure by the inventor prior to filing a patent application.

**The situation in Europe**

According to the European Patent Convention the disclosure of an invention will not risk the validity of a later patent application as long as the European Patent Application (EPA) is filed within 6 months of the original research being disclosed at an officially recognized international exhibition or as a disclosure made as a consequence of evident abuse by the applicant (if, for example, the disclosure of an invention is made despite the existence of a secrecy agreement). Although the second provision is useful, in practice only a handful of exhibitions are ‘officially recognized’ and therefore the usefulness of the first aspect of this provision is minimal.

The 6-month grace period for filing an EPA subsequent to a prior disclosure therefore has limited applications.

One possible solution to this problem might be a ‘provisional’ patent application. Under this system an inventor who does not have all the necessary elements for a patent application could file a summary description of the invention with the patent office, thereby obtaining a period of 1 year to complete the application (which is not published at this stage) after paying a fee. However, the risks of this approach are clear: not only could the invention be disclosed, but it is not clear how ‘provisional’ the extent of the written description must be for a provisional patent application to permit a further year to complete the disclosure. In effect, such a system could cause more problems than introducing a grace period in Europe that is similar to those provided in other countries.

**Summary: the status quo**

The ever-increasing pressure for inventors to publish the results of their work as soon as is practically possible conflicts with the more stringent requirements for a patent application to contain experimental support specifically relating to the invention on file. Although in several countries a grace period exists, in Europe the criteria for the 6-month period of grace means that in effect this provision is of little practical benefit to inventors who have knowingly disclosed the results of their research before filing an application. At this stage, in Europe at least, it is not clear how to fulfil both the need for early publication of scientific findings and the increasing need for adequately substantiated patent applications.

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The Mycogen case relates to a method of genetically modifying a plant cell by forming a T-DNA–plant gene combination. The claims covered the use in any plant cell of any plant structural gene under the control of any plant promoter. The experimental data in the specification, however, related only to the expression of phaseolin in plant cells. Moreover, prior art in the field disclosed the method in theory, but acknowledged that the method had not been performed. In this case claims were granted which were restricted in scope to that of the example. The reasoning followed was that the invention in this case was not “a new general technique but the successful completion of experimentation”.