

PATENT CULTURE SAMPLES: THE 'EXPERT SOLUTION' FOR EUROPE

Inventors applying for patents on microorganisms are typically required to supply a culture sample as part of the patenting procedure. These samples serve to satisfy, in part, the "disclosure requirement" of a patent since a written description of a living organism is generally insufficient to enable another practitioner to duplicate the exact organism. This holds for life forms isolated from nature as well as those created in the laboratory.

Biotechnologists are highly sensitive to placing culture samples in semi-public hands because the culture is, in fact, the invention. It is a minor matter for an experienced technician to begin producing the invention using the sample. Some experts have in fact described microbiological inventions as being "over-disclosed" compared to other patents.

Controlling access to deposited culture samples is then critical to protecting the invention. Control is most essential during the period between the patent application and its issue. Following the grant, remedies for improper use are available. But before that, legal protection is limited, or unavailable altogether.

Access to culture samples during this interim period (typically a minimum of two years) is not a concern in the United States because the sample need not be submitted until, and unless, the patent is granted (see *Bio/Technology* 4:120, Feb. '86). And in Japan and the Netherlands, although deposits are required by the date of the patent application, public release is not granted until the patent is issued. In much of the remainder of the world, where an "early publication" system is used, the inventor is vulnerable to losing the invention. Under early publication systems, the patent application is published 18 months following its initial submission. Hence, if an inventor applies first in the U.S. and a year later in Europe (under a priority claim), publication will occur six months after the European filing. Although the patent has not been granted at that point, the culture—submitted no later than the date of the European applica-

tion—becomes conditionally available to the public as of the publication date. From that time, the inventor is totally dependent on the controlling legislation to prevent unwarranted access to, and use of, culture samples.

Access and use are controlled by national legislation or, in the case of the European nations, by the European Patent Convention (EPC) if the "European patent" procedure is used. Cultures are likely to be stored in one of the international depositories sanctioned under the Budapest Treaty (see *Bio/Technology* 1:801, Nov. '83), but access is determined by the patent laws, not by this Treaty. In Europe, the regulations are in effect until the patent expires, or until the application has been rejected or withdrawn, at which point free general access is permitted.

Access to deposited cultures can be limited to an independent expert.

Until recently, a sample from a culture filed as part of an EPC patent application was available to any person who agreed 1) not to make the sample available to a third party, and 2) not to use it for other than "experimental purposes." European national laws are similar, with some providing the additional restrictions that the samples are not to be exported, nor are they to be granted to residents of countries where patent protection is not being sought. In either case, it has been widely recognized that these conditions are difficult to enforce, making effective control over deposited cultures very problematic.

The patent applicant now has some discretion over access to culture deposits filed under EPC patent applications. Under EPC Rule 28(4) (enacted in 1981), the applicant can request that access be limited to an "independent expert." The independent expert performs experiments on a culture sample at the request of any person willing to pay for the service. With this system, the requester of the experimental service is treated as a

third party, binding the expert not to release the sample directly to him or her. Experts are approved by the patent applicant and by the President of the European Patent Office (EPO), the functioning body under the EPC, from nominations made by the requester of the sample. Use of the independent expert may be mandated until the patent is either granted, withdrawn, or rejected. At that point the general controlling legislation described above becomes effective.

In 1982 the French Patent Office applied this same EPC rule to patents granted nationally. A similar option is available for Swedish national patents. In the remaining European nations, the inventor seeking national patents does *not* have access to an independent expert and must rely on the less enforceable agreement by the requester not to make improper use of the sample.

To date, the EPO has received no requests to release a culture sample to an independent expert. The lack of any experience with this system makes it difficult to gauge the actual amount of protection it provides. The "independent expert" approach does seem to provide assurances not otherwise available, but at present it is available only in France and Sweden, or for 11 (soon to be 14) European nations if patent applications are filed with the European Patent Office.

Selecting the EPC "independent expert" option, however, *does* involve some risk. In countries like the United Kingdom, the disclosure requirement applies to the general public. Inventions covered by the expert system are, however, considered an inadmissible "privileged class," as there is some restricted disclosure allowed. It is not clear whether an EPC patent granted for the U.K. and evoking the expert opinion could be overturned for insufficient disclosure. The matter is presently under review.

In the longer term, the "independent expert" system may be available at the national level in a number of other nations. It certainly deserves consideration. As a compromise in the controversy over who should have access to deposited cultures, it strikes a practical, if not perfect, balance. ▣

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