NOTE**Proposal to change the Rule governing the designation of type strains deposited under culture collection numbers allocated for patent purposes**

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The Rule of the Bacteriological Code governing the designation of type strains held in culture collections under accession numbers issued for the purpose of patent application does not adequately allow access to these organisms for the purpose of comparative taxonomic study. Under the present system the publication of the collection number in the *International Journal of Systematic Bacteriology* (IJSB), thus fulfilling the requirements of valid publication, does not guarantee either that information on the strain is made available, or that access to the strain is made possible (Lapage *et al.*, 1992). The issuing of a culture collection number for a strain held under regulations governing patent applications often requires that all information on the strain be handled confidentially. As a result, despite the fact that an author or authors may publish the collection number in the scientific literature, the culture collections themselves cannot supply information on the strain itself, nor who deposited it. The consequence is that the scientist who wishes to obtain the strain must either contact the author(s) or depositor(s) of the strain, or consult the patent application. In the case of the latter two it is assumed that the scientist knows both the depositor and/or the patent application.

Science and taxonomy are dependent on the reproducibility of results and the availability of the object(s) of study (in this case micro-organisms) for comparative study. In the majority of cases type strains are obtainable directly from culture collections that are in the position to supply details of the presence of the strain, together with its strain history. This information is now widely available via printed or electronic catalogues, or by direct correspondence. In the case of strains deposited for the purpose of patent applications the scientist is required to undertake a further search in order to determine whether the strain can be made

available. The onus is thus on the scientist who wishes to have the strain to prove that it exists and not with the depositor(s) and describer(s) of the strain to provide access to the organism used in the scientific literature. The greatest difficulties at present are that a direct request to the depositor may simply be ignored, or that the author has since moved to a new address and does not receive the enquiry. Furthermore, the search of the patent literature is difficult because

- (i) a search would only be possible when patents are granted and/or laid open,
- (ii) the process to be patented is important and is usually indexed, while the culture collection number and name of the strain is of secondary importance and is rarely indexed.

The Guidelines for Authors for the IJSB now makes clear reference to how 'patent strains' are to be cited in articles:

'Authors should inform the Editors, and must indicate in the paper, whenever strains under study are involved in a patent process. Strains other than the type strain should carry the superscript "PP" if a patent is pending and "P" if a patent has been issued for a type or any other strain. The description of a new species cannot be published while a patent is pending upon the intended type strain because that strain would not be available for study. In this circumstance, authors are to wait until the patent is issued.'

It should be noted that the term 'patent pending' is largely in use in North America and its international equivalent term is 'patent application', while 'patent issued' is equivalent to the international term 'patent published and granted'. In the remainder of this article, these terms, which have wider usage, will be used.

Despite this requirement, type strains have been designated within the last year in the IJSB, both as original articles and for inclusion in the 'Validation Lists' for which culture collection numbers have been issued, but information on these organisms cannot be made available by the culture collection. Restricted access to information on such strains indicates that the culture collection has entered into a confidentiality agreement with the depositor(s), which may be interpreted as indicating that the organism has been deposited either under some kind of restricted access (c.f. 'safe deposit'), or as part of a patent application. Should these organism be deposited under a patent application they must, according to recent changes in the Code, be designated ^{PP} (patent application) or ^P (patent published and granted). Strains bearing the designation ^{PP} cannot be used as type strains and any proposal to make them type strains is illegitimate. However, a 'patent strain' which clearly does not bear the designation ^P is not also contrary to the Code, since this is only a requirement of the IJSB and does not provide an easy solution when authors choose not to conform to these instructions, further hindering taxonomy.

The present Rule 30 (Labeda, 1997a, b), which is supposed to govern the use of patent strains, does, in fact not deal with this directly, and now states:

'Rule 30

For the name of a species to be validly published it must conform with the following conditions.

- (1) It must be published in conformity with Rules 27 and 28b.
- (2) It must be published as a binary combination consisting of a generic name followed by a single specific epithet (see Rule 12a).
- (3) The description must include a designation of a type strain, and, if the bacterium is cultivable, a living culture of that strain must be deposited in at least one of the permanently established culture collections, from which subcultures must be available. The designation(s) allotted to the strain by the culture collection(s) must be quoted in the published description.
- (4) Patented bacteria may serve as type strain and must also be deposited as in (3) above, but if a patent is not yet awarded or not yet laid open, the publication of a name and a description must be deferred until the patent is awarded or subcultures made available. Any type strain for which a patent is pending must also be so identified when the name is proposed.'

In its present form Rule 30 does not deal with the question of how to deal with either 'patent strains' which the depositor does not release or the case of organisms otherwise held under restricted access.

In order to clarify the situation, the following ad-

ditional changes are proposed with respect to the way in which 'patent strains' are used as type strains.

The use of 'patent strains' as type strains under Rule 30.

'(4) Strains bearing numbers issued as part of a patent application must be clearly designated ^{PP} (patent application) or ^P (patent published and granted) at the time of valid publication in the IJSB. Strains bearing the designation ^{PP} cannot be used as type strains. In order to make possible access to the strains which bear the designation ^P an unambiguous reference should be given to the patent published and granted in the list of references supplied at the time of valid publication in the IJSB. Failure to designate such strains with the superscript ^P and to include documentary evidence that the strain can be made available contravenes the present Code.

Note: this does not apply to type strains held in culture collections which are, subsequent to their initial deposit in the collection, subject of a patent application and are not then subjected to restricted access.

(5) Strains held in culture collections under agreements, other than patent applications, in which confidentiality of information on the strain and limited access to the strain has been guaranteed on the part of the collection cannot be designated as type strains.

Note: this does not include 'Material transfer agreements' or restrictions placed on the distribution of the organism based on risk group assessment, import or export regulations.

Example: *Lactobacillus panis*, the type strain of which is DSM 6035, is illegitimate.'

It should be noted that there are several type strains which have, subsequent to their deposit in a culture collection (without restrictions placed on them), been the subject of patent applications and are in unrestricted circulation. In these cases there would appear to be no conflict between the requirements of taxonomy, of unrestricted access to type strains, and the need of industry to protect their intellectual property. A practical solution for patent applicants and those wishing to contribute to taxonomy is that the strain could be deposited under a second number which does not relate to the patent application. In formulating the present changes it is not the intention to limit the retroactive effects of these proposed changes. In the case of those species (largely within established genera) which would be made illegitimate by these changes, submission of the name, together with the appropriate published and granted patent application, for a limited period of 1 year after acceptance of this change, would provide a simple solution to the problem. Such formal paper work may be irritating, but much less so than type strains which are not in circulation.

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