UK Practice Regarding Sufficiency of Disclosure (April 2022)

Section 14(3) of the United Kingdom's Patents Act 1977 (as amended) requires that:

"The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art."

This fictitious person skilled in the art (or team) is considered uninventive but technically competent. Consideration of sufficiency amounts to a consideration of whether the applicant has provided an enabling disclosure of their invention. An enabling disclosure does not mean that a patentee has to demonstrate that every embodiment within the scope of the claim has been tried, tested and proved to have been made. Applicants may rely on a general principle of application to satisfy the sufficiency requirement (if one exists). Insufficiency is judged at the filing or priority date of an application rather than the date of publication. There is no requirement in the United Kingdom that the applicant must indicate the best method for carrying out the clamed invention.

A summary of the relevant principles to be applied when determining whether a patent application satisfies section 14(3) of the Patents Act 1977 is set out in *Eli Lilly v Human Genome Sciences* [2008] RPC 28:

"The specification must disclose the invention clearly and completely enough for it to be performed by a person skilled in the art. The key elements of this requirement which bear on the present case are these:

(i) the first step is to identify the invention and that is to be done by reading and construing the claims;

(ii) in the case of a product claim that means making or otherwise obtaining the product;
(ii) in the case of a process claim, it means working the process;

(iii) sufficiency of the disclosure must be assessed on the basis of the specification as a whole including the description and the claims;

(v) the disclosure is aimed at the skilled person who may use his common general knowledge to supplement the information contained in the specification;

(iv) the specification must be sufficient to allow the invention to be performed over the whole scope of the claim;

(vii) the specification must be sufficient to allow the invention to be so performed without undue burden."

Under UK practice a distinction is often drawn between three broad types of insufficiency:

(1) Classical insufficiency – there is no enabling disclosure whatsoever. An example might be a claim to a material having a particular structural property, such as porosity, or crystal structure, where there is no disclosure of how this property might be achieved in practice.

(2) Insufficiency by ambiguity/uncertainty – the teaching in the specification is not clear enough to know whether someone has worked the invention or not. An example might be a claim to a material having a particular physical property which requires a known reference/standard in order to calculate that property and the reference/standard is not provided.

(3) Insufficiency by excessive claim breadth – there is enabling disclosure of only part of what is encompassed within the claims.

The skilled person is someone seeking to make a patent work and may use their common general knowledge at the filing date to supplement the information contained within a specification. Therefore, worked examples in specifications can omit certain basic steps if these can be derived by routine trial and error, and can include obvious mistakes if the skilled person could be expected to spot and correct them. However, the skilled person must not require any inventive skill or engage in experimentation that would be an ‘‘undue burden”. There is no precise definition of what constitutes an undue burden, but it can be equated with the need for more than routine (i.e. excessive) experimentation. Post published evidence is allowed to demonstrate that the patent was sufficient at the date of filing of the application, but it cannot be used to render an insufficient patent sufficient.

Chemical Art

Chemical compounds defined by Markush Formula: if a claim is to a broad class of compounds defined by a Markush formula, then to be sufficient the specification must identify, a) the characteristics of that class (all of the compounds claimed must fall within that class), and, b) a method of manufacture of the class. However, where a claim relates to a single compound only, only one method of making that compound is required for enablement of a claim to that product, even if other methods are available (*Generics v Lundbeck* [2009] RPC 13).

Stereoisomers (enantiomers, diastereomers, Cis-trans and E-Z isomerism: in the UK where a product has only been available as a racemate and not as a single enantiomer, the single enantiomer is deemed not to have been made available to the public (due to lack of an enabling disclosure) and thus does not form part of the state of the art. Enablement for polymorphic forms must include some evidence that they are not the only crystalline form and (to be the basis of a non-obvious invention) should have evidence of the advantage associated with the polymorph.

Prodrugs and metabolites etc: If a class of new compounds is well defined and the functional groups which may be readily derivatised are similarly clear then esters, ethers, salts and N-oxides may well be deemed enabled (e.g. where acids or alcohols are clearly defined and can be readily produced given the information is the application as filed then simple esters and ethers are likely to be deemed supported). Where the sites of derivatisation are not self-evident then these functional groups are likely to be regarded as not enabled in the absence of relevant synthetic examples. Similarly, enantiomers or other isomers (though frequently not regioisomers) are likely to be supported (i.e. a claim need not be limited to one particular isomer) where it is clear that the synthesis/syntheses will allow access to all isomers. Where a technical prejudice exists in the art to obtaining a particular isomer then an application claiming that isomer must be enabled i.e. that technical prejudice must be overcome (c.f. *Generics v Lundbeck*). Undisclosed prodrugs are by their nature not likely to be enabled unless the metabolic pathway of the compounds of the invention is either disclosed or well understood according to the common general knowledge.

New use of a known compound: For patents relating to a second medical use of a known substance or composition, the specification as filed must make it plausible that the substance or composition will be effective for the claimed use or uses; if not, the patent will be insufficient. A claim to a class of products said to possess a useful activity must be based upon the identification of a common principle (a principle of general application) which permits a reasonable prediction to be made that substantially all the claimed products do indeed share that activity. It is not permissible to by-pass that requirement simply by adding a functional limitation which restricts the scope of the claim to all products which 'work' (*Novartis AG v Johnson & Johnson* [2009] EWHC (Pat) 1671). There is a three step test for this: identify what falls within the scope of the claimed class; identify what it means to say that the invention works; and determine whether it is possible to make a reasonable prediction that the invention will work for substantially everything falling within the scope of the claim (*Fibrogen v Akebia Therapeutics Inc*.[2021] EWCA Civ 1279).

Microorganisms

The specific provisions concerning microorganism patents and sufficiency are found at s.125A of the Patents Act 1977 (as amended) and Rule 13(1) and related Sch. 1 of the Patents Rules 2007. S.125A concerns "availability of samples of biological material", and as set out in s.130 of the Act, the definition of biological material includes microorganisms. At the international level, the UK is a party to the Budapest Treaty.

For a claim to a microorganism to be considered enabled, it must have been deposited at an international depository authority and the deposit appropriately acknowledged in the application. It is open to the applicant to argue that a deposit is not required and the specification gives sufficient directions to enable the invention to be performed. If, however, this argument is rejected, it is not possible to rectify the situation after the date of filing of the application.

Assessment of whether a deposit has been made is therefore part of the examination process for applications relating to specific microorganisms, with the applicant being informed they have sixteen months from the priority date to add any missing deposit information (but not to make the deposit itself, which must be made before the priority date for any priority claim to be valid). Some assessment of the validity of deposit information is done insofar as it is possible. However, as the deposit may not necessarily be in an open part of the collection, and may not appear in the public catalogues, full forensic assessment of the validity during examination is not possible or reasonably practical.

The remaining general approach to microorganism claims is set out in paragraphs 158-160 of the Examination Guidelines for Patent Applications Relating to Biotechnological Inventions (the 'Biotech Guidelines') as published by the Office.

Artificial Intelligence

UK law does not impose any additional or special requirements concerning the disclosure of AI inventions, beyond the principles discussed above. Whether an AI invention meets these disclosure requirements is determined by considering each case on its own merits, this includes issues relating to so called ''black box'' disclosures i.e. when the creator of the algorithm which the AI uses does not know how the AI algorithm derives its output. If a "black box" invention is found to fail to meet the relevant requirements, then an objection to insufficient disclosure would necessarily arise.