

1. These comments on the Revised Interim Guidelines for Examination of Patent Applications Under the 35 USC 112 para. 1 "Written Description" Requirement ("the Interim Guidelines") are submitted on behalf of the BioIndustry Association ("BIA"). The BIA is the trade association of the bioscience industry in the United Kingdom and has over 200 members. As users of the US patent system and other patent systems in the industrialised world, its members are keen to see fair and proportional patent protection on a level playing field. BIA members are active in licensing their products to US-based companies and exporting technology to the US, as well as participating in flows in the opposite direction.

2. The BIA submitted comments on the first interim guidelines on 4 November 1998.

3. The BIA broadly welcomes the revised interim guidelines, which seem to include many improvements over the first proposal. In particular, it welcomes the approach of writing the guidelines in a technology-neutral fashion, and the avoidance of over-particular examples.

4. There are two points on which we would like to comment further. First, in our comments on the first interim guidelines, we stated that it should be of overriding importance to enquire whether the scope of the claims is fair, having regard to the contribution that the applicant has made to the art and having regard to the state of the art. In response to that, the Office said: 'The Office is bound to follow the law and cannot make judgment calls as to what is "a fair reflection of the applicant's contribution to the art"'. With respect, this misses the point of our previous comment, which is directed to the policy underlying the law. We again commend the enquiry as being an important tool in helping to arrive at just decisions which are fully consistent with the law as expressed in the statute and interpreted by the courts.

5. Secondly, while we note with approval that examiners are enjoined by the proposed guidelines to carry out their tasks with thoroughness and care, the reality is that that will only happen if the examiners are given enough time to do their job properly. As we said in our previous comments:

"PTO personnel should be encouraged to undertake their tasks carefully and thoroughly, and should not be penalised for taking an appropriate amount of time to do so. Any reward or remuneration scheme for examiners should take into account the complexity of many bioscience

patent applications and should not encourage, however inadvertently, a rapid but nonetheless incomplete review."

Respectfully submitted

Andrew G. Sheard
Chairman, Intellectual Property Advisory Committee
BioIndustry Association
14/15 Belgrave Square
London SW1X 8PS

Phone: +44-20-7565-7190
Fax: +44-20-7565-7191
Email: admin@bioindustry.org
Web: www.bioindustry.org