Review of the Research Exemption ('Bolar') Provision as set down in Section 42(g) of the Patents Act 1992.

The Department is inviting comments from interested parties on a proposal to broaden the scope of the "Bolar" type research exemption provision as set down in Section 42 (g) of the Patents Act, 1992.

Background:
During the consultation on the Review of the Patents Act, 1992 it was suggested that the current wording of Section 42 (g) places certain companies carrying out research in Ireland at a competitive disadvantage, and, may interfere with Ireland's ability to attract Pharmaceutical/Biopharmaceutical companies to invest here. In light of such concerns it is deemed appropriate to undertake a separate consultation process to ascertain the view of stakeholders on a proposal to expand the exemption provision.

The Research Exemption Provision:
In all EU Member States before drugs for human use are put on the market, the product must have a marketing authorisation. In Ireland, such market authorisations are granted at the national level by the Irish Medicines Board and at EU level by the European Medicines Agency using the centralised procedure.

In order to obtain a marketing authorisation, the manufacturer of a medicinal product must submit data to prove the safety and efficacy of the product. This data is generated by conducting clinical trials and tests. In certain circumstances, manufacturers of generic products may rely on data submitted by the original manufacturer when applying for an authorisation for their products. However, if they manufacture the original product during the course of such trials, for example to demonstrate similarity, they may leave themselves vulnerable to an infringement action if the original product is protected by a patent or a supplementary protection certificate. This led to such tests being carried out in countries where there is no risk of infringement proceedings e.g. US, Canada and India.

To address this legal uncertainty in the EU, a provision was inserted in the Directive 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use by the insertion of a new Article 10(6) in the Directive. This provision creates an exemption from patent infringement for certain acts carried out by generic manufacturers with a view to obtaining an authorisation for a generic medicinal product. This is known as a "Bolar" type provision after the legal case in the U.S. which prompted its introduction in that jurisdiction. (A similar provision was inserted for veterinary medical products[i]).

Implementation of the Exemption Provision:
Ireland transposed the exemption provision by way of S.I No. 50 of 2006 "European Communities (Limitation of Effect of Patents) Regulations 2006. The exemption provision was intended only to protect the generic industry from possible infringement of a patent when carrying out trials for market authorisation. It was left to each individual Member State to interpret the provision with the result there is a disparity between Member States and it is recognised that the different interpretation of the exemption provision has created an imbalance within the EU especially in relation to clinical trials and research carried out by innovative companies.

Also only studies and trials needed for filing applications for a marketing authorisation in the EU fall within the scope of the provision. The use of trials information or production for applications outside of the EU seems to be excluded.

Ireland, like the UK took the literal interpretation of the provision as set down in the Directive. Some other countries opted for broader interpretation and implemented the exemption provision beyond the Directive.

Extension of the Research Exemption Provision:
The aim of the new proposal will be to broaden the scope of the exemption provision, for both medical products for human use and veterinary medical products, as set down in Section 42(g) (i) and (ii) of the Patents Act 1992. Specifically, it is proposed to extend the exemption to-

(i) include all studies/tests/ experiments/clinical/field trials and the consequential practical requirements which are necessary for the purpose of obtaining a market authorisation for a new as well as a generic product (i.e. carrying out tests on a combination product where one of the components is patented by a third party),

(ii) cover acts done in this country relating to the acquisition of a marketing authorisation in a non-EU country.

These proposed changes would necessitate primary legislative changes to the Patents Act 1996 as such exceptions go beyond the Directive, but would bring our legislation more in line with those countries who have a more liberal exemption system in place.

Comments on the proposed legislation changes should be submitted by e-mail to ipu@djei.ie or in writing by **14th April 2012** to:

Imelda Hardiman,
Intellectual Property Unit,
Department of Jobs, Enterprise and Innovation,
Kildare Street,
Dublin 2

Confidentiality of Submissions:
Contributors are requested to note that it is the Department's policy to treat all submissions received as being in the public domain unless confidentiality is specifically requested. Respondents are, therefore, requested to clearly identify material they consider to be confidential and to place same in a separate annex to their response, labeled "confidential". Where responses are submitted by email, and those emails include automatically generated notices stating that the content of same should be treated as confidential, contributors should clarify in the body of their emails as to whether their comments are to be treated as confidential.

Relevant provisions of Freedom of Information Act 1997 (as amended):
Respondents' attention is drawn to the fact that information provided to the Department may be disclosed in response to a request under the Freedom of Information Acts. Therefore, should you consider that any information you provide is commercially sensitive, please identify same, and specify the reason for its sensitivity. The Department will consult with any potentially affected respondent regarding information identified as sensitive before making a decision on any Freedom of Information request.

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[i] Directive 2004/28/EC amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products by the insertion of a new Article 13(6) in the 2001 Directive. See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0028:EN:HTML