An Roinn Post, Fiontar agus Nuálaíochta
Department of Jobs, Enterprise and Innovation

Summary of Responses to the Review of the Research Exemption ('Bolar') Provision

Background

In all EU Member States before drugs for human use are put on the market, the product must have a marketing authorisation. A manufacturer must submit data to prove the safety and efficacy of the product in order to obtain a marketing authorisation, usually by means of conducting clinical trials and tests. In certain circumstances, manufacturers may produce the original during such trials, for example to demonstrate similarity, leaving themselves vulnerable to accusations of patent infringement. Such risks may have led to such tests being carried out in countries where there is no risk of infringement proceedings e.g. US and India.

To address this legal uncertainty in the EU, a provision was inserted in the **EU Directive 2004/27/EC** amending **EU Directive 2001/83/EC** by the insertion of a new Article 10(6) in the latter 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.

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 that there is a disparity between Member States differing interpretations and legal implementation.

In addition, only studies and trials needed for filing applications for a marketing authorisation in the EU fall within the scope of the provision.

Consultation

Recently the Department of Jobs, Enterprise and Innovation held a Review of the Research Exemption ('Bolar') Provision as set down in Section 42(g) of the Patents Act, 1992.

This review is a separate consultation process from the recent, more general Review of the Patents Act 1992, to examine if the current legislation placed certain companies carrying out research in Ireland at a competitive disadvantage, and/or interfered with Ireland's ability to attract pharmaceutical/biopharmaceutical investment. Furthermore, the review undertakes to ascertain the views of stakeholders on a proposal to expand the exemption provision.

The consultation document was circulated extensively electronically to patent practitioners and the biopharm sector as well as the Department's website. The original deadline of 14 April 2012 was extended to 20 April. A total of four responses were received. All the

responses were supportive of a change in the primary legislations, the Patents Act, 1992, to broaden the scope of the current exemption as set down in Article 42(g) of the Act.

While Ireland transposed the exemption provision in accordance with the EU Directive and inserted the exact legal language in to Irish law, other Member States employed a broader interpretation of the exemption. Some respondents maintained that this has resulted in a competitive disadvantage for Ireland in this area.

Responses suggested it would be useful to clarify the existing exemption, while also expanding the exemption to include other elements including;

- studies, text, experiments, clinical trials, field trials, and the consequential practical requirements necessary for the purpose of obtaining market authorisation
- acts done in Ireland relating to the acquisition of a marketing authorisation in another country.

Next Steps

The Department of Jobs, Enterprise and Innovation is now studying these responses and is drafting a Regulatory Impact Assessment. This will provide an overview of the issues raised and will set out the appropriate action to take.

Intellectual Property Unit
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