April 2017

EFCG Briefing Note

The Bolar Exemption

The "Bolar" exemption was introduced in the EU law in 2004 by article 10(6) of Directive 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

The objective of the Bolar exemption is to ensure that once the intellectual property rights of a medicinal product expire, a generic medicine can become available without undue delay. Under the Bolar exemption the activities required to obtain regulatory approval of a generic medicine can be carried out without constituting an infringement of the intellectual property rights of the originator – being those, the rights associated with the patent or with the Supplementary Protection Certificates (SPCs).

This means that according to the objectives of the Bolar exemption, manufacturers of Active Pharmaceutical Ingredients (APIs) and generic medicines should be allowed to carry out in all EU Member States the activities required by the health authorities to obtain regulatory approval allowing the generic medicine to become available immediately after the expiry of the intellectual property rights of the originator.

EU Member States have interpreted the Bolar exemption in different ways, leading to inconsistencies in its application by the national courts. In certain cases the way it was implemented and subsequently interpreted by relevant jurisdictions led to situations that are the opposite of the directive's original objective. Moreover, uncertainties remain in some Member States as to whether the Bolar exemption does apply to activities which are carried out in view of obtaining a market authorisation abroad, be it in another EU Member State or not.

The current situation creates a high level of unpredictability on the process and timelines required to make generic medicines available to patients.

In this context, the European Commission has suggested that the Bolar exemption might be updated. The European Commission Communication titled "Upgrading the Single Market: more opportunities for people and business", published on 28 October 2015, states that "**An update of the scope of the EU patent research exemption would lead, among other things, to a smooth supply of active pharmaceutical ingredients throughout the Single Market**".

The European Fine Chemicals Group (EFCG) has consistently advocated and fought for:

- Strict compliance with the applicable Intellectual Property rights as these are the incentive for the development of innovative medicines that have the potential to improve mankind's health.

- Predictable and timely introduction of generic medicines as these are essential to the accessibility to medicinal products and to ensure the sustainability of the Public Health sector.

- A level playing field, where EU Manufacturers of Active Pharmaceutical Ingredients and medicinal products are at no advantage over manufacturers located on outside EU countries – but are also not placed on a situation of disadvantage vis a vis outside EU manufacturers due to poorly conceived or implemented regulations.

Based on this the EFCG Supports the European Commission's Single Market Strategy for Europe and its efforts to harmonise and clarify the implementation of the Bolar clause across EU member states.
This clarification should protect the original objective of the Bolar exemption and broaden its scope by:

- Removing any uncertainties as to which activities constitute an infringement of Intellectual Property rights, thus avoiding costly litigations which increase the costs for both originators and generic medicines

- Allowing Active Pharmaceutical Ingredients manufacturers **across EU Member States** to develop, manufacture, supply and sell Active Pharmaceutical Ingredients still under intellectual property protection for R&D purposes and for the purpose of obtaining the regulatory authorisations required for the prompt availability of the generic medicine upon expiry of the intellectual property rights

- Allowing pharmaceutical companies to acquire and purchase Active Pharmaceutical Ingredients still under intellectual property protection with the purpose of conducting all the required development activities, studies and trials that are required to obtain a Marketing Authorization from the applicable regulatory authorities hence ensuring the prompt availability of generic medicines upon expiry of the intellectual property rights

About EFCG

EFCG was formed in 2004 to be the focus, the forum and the voice of the European fine chemicals and Active Pharmaceutical Ingredients manufacturers. We are a non-profit international sector group within Cefic - the Brussels-based European Chemical Industry Council.
EFCG represents over 100 organisations with over 200 manufacturing sites.