



The Malta Bolar Provision

An Incentive for Investment and Innovation?

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The Bolar Provision typically defines circumstances in which the proprietors of a patent are precluded from preventing third parties from performing acts which are otherwise protected by patent law.

The Bolar provision originated in the United States, by virtue of the judgment *Roche Products v Bolar Pharmaceuticals*¹. This judgement had limited the scope of the 'experimental use exemption' to the experimental use of a patented article for the sole purpose of 'philosophical experiments'², curiosity, or for mere amusement.

In response to this judgement, the US Congress introduced the Hatch-Waxman Act³, which allowed the use of patented material for uses reasonably related to the development and submission of information pursuant to the regulatory laws concerning the use or sale of drugs.

The present position in Europe is that the nature of what constitutes experimental use is left to the discretion of individual EU Member States.

Malta has fully embraced the extensive reach of the so-called *Bolar Provision*. Malta has been very pro-active in this regard; the *Bolar Provision* was implemented into Maltese law in 2003, even prior to its accession to the EU.

The Maltese Patent and Designs Act⁴ extends the exemption to purely experimental purposes and scientific

research, acts done privately and for non-commercial purposes as well as to acts done for the development and presentation of information as required under Maltese or foreign legislation regulating the production, use or sale of medicinal or phytopharmaceutical products⁵.

A brief comparative analysis of various EU member states serves to show that, whilst a few countries such as Poland have interpreted the Bolar provision in a wide manner similar to Malta, others have adopted a restrictive interpretation of the provision.

For instance, the UK Patents Act 1977⁶ qualifies '*experimental purposes*' as being those '*relating to the subject-matter of the invention*'.⁷

In *Monsanto v Stauffer*⁸, the Court of Appeal held that tests conducted in order to demonstrate that a product or process works as claimed were held not to qualify as experiments under the exemption because they do not relate to 'the subject matter of the patented invention'.

Under Maltese law experiments and scientific research per se are permitted; generic companies may carry out experiments and clinical trials for the purposes of obtaining regulatory approval

¹ 733 F.2d 858 (Fed. Cir. 1984).

² Ibid.

³ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 1984 Stat. 1538.

(codified as amended in scattered sections of 21 & 35 U.S.C.).

⁴ Chapter 417 of the Laws of Malta.

⁵ Article 27 of the Patent and Designs Act, Chapter 417 of the Laws of Malta.

⁶ As amended up to and including 1 January 2010

⁷ Art.60 (5)(b) of the UK Patents Act 1977

⁸ [1985] RPC 515 CA.

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prior to the expiration of the lifetime of the patent concerned.

Upon the expiration of the patent of a competitor's product and the obtainment of the regulatory approval, a generic manufacturer may market his products without undue delay. In the light of the highly competitive nature of the pharmaceutical industry where time is of the essence, Malta's positive approach towards this exemption the Bolar exemption has proved to be a significantly competitive edge over other countries which opted for a more restrictive approach.

Considering the number of pharmaceutical companies which re-locate to Malta on an annual basis, it is clear that the Maltese interpretation of the Bolar provision has, and remains to be, a great advantage. Permitting generic companies to perform research tests and experiments without falling in the realm of patent infringement, has attracted key players.

The adoption of a broad interpretation of the Bolar exemption and having a strong Patent Law proves to be a prime source of attraction for FDI and a positive incentive for innovation, whilst at the same time protecting brand owners against abuse.

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