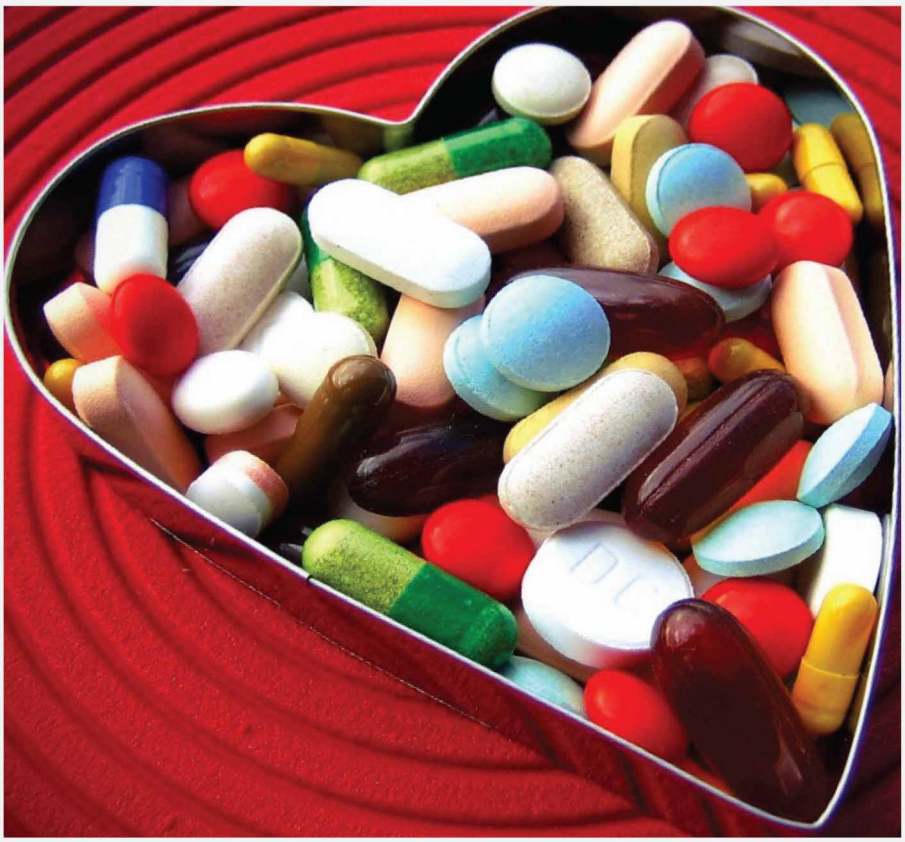

The manner in which Malta has adopted the Bolar Exemption has attracted reputable pharmaceutical companies to establish themselves within our shores. The journal explores the Bolar Exemption, with particular emphasis on the safe harbours that the exemption presents in different countries.

Malta's Bolar Exemption:
an Incentive for Investment and Innovation

Maria Chetcuti Cauchi

In light of TRIPS and the general rule that if a specific country's legislator wishes to promulgate a new exception, it must meet these tests set out in Art. 30, not long after the entry into force of the TRIPS Agreement, the Regulatory Review exception and the Stockpiling exception were put to test at the WTO in the Canada-Generics dispute in 2000.

In its decision, the WTO Panel introduced a vital legal test in its interpretation of a "limited" exception as listed by Art 30. Under this test the Panel found that the Stockpiling exception was not "limited" and therefore not in conformity with Art. 30 TRIPS. However, by contrast, the Regulatory Review exception was deemed to be "limited" and in accordance with TRIPS. Hence, to put it plainly, the Regulatory Review exception was found to be "WTO approved" and open to Members to adopt without running risks of challenge by any other Member.

Malta availed itself of this opportunity and introduced the Regulatory Review Exemption/ Bolar exception in Article 27 (6) (a), (b) and (d) of its Patents and Designs Act.

The Bolar Exception

A simple definition of this exception provides that one could make use of a protected invention relating to a pharmaceutical product, BEFORE the expiration of the patent, in order to carry out tests and obtain health authority approvals, for the purposes of commercialising a generic version just after the expiration of the patent.

This means that despite the general rule that patent registration affords a right-holder the right to prevent, for twenty years, third parties from performing any acts which incorporate the subject-matter of the patent, by way of exception; testing and clinical trials may be carried out for experimental use before such expiry. The purpose behind this exception is to assist generic companies to place their product on the market as soon as the patent expires, without wasting any precious time and hence allowing consumers to obtain such pharmaceutical immediately at a much lower price.

International Analysis

It is worth noting that although the Bolar exemption has been incorporated by a number of countries, they have done so to different extents and with different variances of interpretation. Hereunder is a short comparative study of such adoption into other jurisdictions.

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- *The purpose behind this exception is to assist generic companies to place their product on the market as soon as the patent expires, without wasting any precious time and hence allowing consumers to obtain such pharmaceutical immediately at a much lower price.*

the United States

The Bolar provision originated in the United States, by virtue of the judgment Roche Products v Bolar Pharmaceuticals and from which the title of this exemption is derived. In this judgement, experimental use was construed narrowly and only to satisfy acts performed for amusement and for strictly philosophical inquiry. In fact, the court denied Bolar the right to begin the FDA (Food & Drug Administration) approval process before the expiration of the patent.

Subsequently, the US Congress introduced the Drug Price Competition and Patent Term Restoration Act of 1984 , usually referred to as the Hatch-Waxman Act, which was designed to promote generics while leaving intact a financial incentive for research and development. The Act attempts to strike a balance among competing interests (particularly, innovator and generic pharmaceutical companies). This Act 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. This would result in lowering the costs of health care by permitting generic drug manufacturers to seek such approval prior to the expiration of the braded drug patent.

Section 271(e)(1) of the Hatch-Waxman Act was intended to overrule the Roche decision and to exempt from infringement the bio equivalency testing needed to secure FDA approval of generic drugs.

the EU

Until a few years ago, the question of "testing on a non-expired patent" was not harmonised at EU-level. This resulted in different interpretations as to whether clinical trial work carried for generic drug approval was deemed to be patent infringement in accordance with the individual national laws of the Member States. Seeking to rectify this situation, and harmonise exemptions throughout the EU, on 11 March 2004 the EU adopted a new European pharmaceutical regulatory directive . The aim of this directive was to facilitate the movement of generic products to the European market and had to be implemented by national jurisdictions by October 30, 2005.

This Directive introduced a "Bolar-type exemption" regarding "the necessary studies and trials and the consequential practical requirements" carried out in order to obtain regulatory approval for the EU. Experiments and trials, for the attainment of regulatory approval for a generic or a biosimilar are explicitly part of the exempted trials.

As with all directives, implementation in national laws does not necessarily have to be identical in every Member State – however there is a minimum threshold that each country has to conform to. Below is an analysis of the variances between different member states, always subject to the minimum levels required by the EU.

the United Kingdom

The UK has narrowly interpreted the Bolar exemption. Many times UK court decisions need to be relied on for the interpretation of the terms 'experimental purposes' and 'subject matter of the invention'. The most replied on case is Monsanto/Stauffer which, although nearly 30 years old, is still an authority in this regard.

Stauffer intended to undertake field trials using a herbicide that was known to infringe a patent held by Monsanto. The intent was to obtain regulatory clearance for this product. However, the courts established that experiments carried out for the purpose of gaining regulatory approval or market authorisation for a product would not be exempt and would still be regarded as acts of infringement in the UK since such work cannot be regarded as 'purely experimental'. In this context, 'experiments' carried out to find out something 'new' and which would be regarded as advancing scientific knowledge, may qualify as exempt as long as they relate to the subject matter of the invention.

Therefore, it is clear that the UK adopted a narrow, limited stance: experiments that are carried out to develop scientific knowledge and learn 'something new' can be exempted from being classified as an infringement, in so far as these experiments have a 'direct' link with the invention described in the patent. Nevertheless, and as juxtaposed to the US position, experiments performed solely for the attainment of regulatory consent, such as field trials or clinical trials, are, generally not considered exempt and would be classified as an infringing act.

France

Contrary to the UK, France adopted a wide definition to the Bolar exemption. The rights afforded by the patent shall not extend to:

- Acts done privately and for non-commercial purposes;
- Acts done for experimental purposes relating to the subject matter of the patented invention;
- The extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared,
- Studies and trials required to obtain a marketing authorisation for a medicament and all acts required for their realisation and to obtain the authorisation,
- Objects to be launched in the extra-atmospheric space which are introduced within the French territory.

Thus, according to these provisions, all acts required for obtaining a French marketing authorisation, including trials, are not infringing.

Germany

Germany also embraces a broad interpretation of the Bolar provision, allowing clinical trials to be pursued under the general experimental exemption rule on a case by case basis.

Conclusion

The Maltese adoption of the Bolar exemption into our laws is deemed to be very wide in its nature. The Bolar provision has been implemented into our laws as follows:

Notwithstanding subarticles (1) and (2), the proprietor of a patent shall have no right to prevent third parties from performing the acts referred to in subarticles (1) and (2)(b) in the following circumstances: ...

(b) where the act consists of making or using such product for purely experimental purposes or for scientific research; ...(d) when an act is done for purposes which can reasonably be related to the development and presentation of information required by the law of Malta or any other country that regulates the production, use or sale of medicinal or phytopharmaceutical products ...

Therefore, experiments and scientific research are permitted in a wider manner, and there is no delving into the ultimate use of such experiments. Malta does not merely permit use for experimental and scientific purposes, but extends the exemption to private and non-commercial use and for the development and presentation of information.

The two main reasons why Malta has been so successful in attracting generic pharmaceuticals companies are the fact that there is a relatively small number of Malta registered patents and the inclusion of a broad Bolar provision into our law.

Malta's stance vis the Bolar exemption and its adoption in the widest form possible stems from the economic need to support the local generics manufacturing industry and the containment of healthcare costs.

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 in the generic industry whilst at the same time protecting brand owners against abuse.

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