December 2017

Global Patent Prosecution Newsletter

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW
SKGF.COM

A U.S. Perspective on Global Strategy

Worldwide Bolar Exemptions

Many countries have exemptions for patent infringement for a product and/or process that is not being used for direct commercialization and profit. For biopharmaceuticals, this exemption, commonly known as a "Bolar exemption", permits activities with a commercial benefit as long as the activities are reasonably related to obtaining information relevant to a submission for regulatory approval. The December 2017 issue of Sterne Kessler's Global Patent Prosecution Newsletter includes information on Bolar exemptions worldwide.

Sterne Kessler's Global Patent Prosecution Newsletter is designed to help meet the needs of biotech/pharmaceutical companies regarding global patent prosecution strategies. For more information, please contact Paul Calvo or John Covert. If you wish to unsubscribe from this and other newsletters, please click on the unsubscribe link below.

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Bolar Exemptions in North America

By: Paul A. Calvo, Ph.D.

Bolar exemptions in the U.S.

Because approval by the U.S. Food and Drug Administration (FDA) is a long, sometimes arduous process, U.S. law provides a research or experimental use exemption with respect to regulated products. Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") which created the Section 271(e)(1), which is often referred to as the "Safe Harbor" or "Bolar" exemption.

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Bolar Exemption in Europe and Asia

By: Paul A. Calvo, Ph.D.

Bolar exemption in Europe

The Bolar exemption is governed by European Directive 2001/83/EC on the Community Code relating to medicinal products for human use. Article 10(6) excludes from infringement of patent rights or supplementary protection certificates (SPCs): “Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4.”

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Worldwide Bolar-type Provisions*

By: Paul A. Calvo, Ph.D.

Country	Recognizes Clinical Trial Exemption	Exemption Covers New Drugs as well as Generics/ Biosimilars?[1]	Ability to Export Data for Authorization in Foreign Jurisdiction?[2]
Argentina	No[3]	n/a	n/a
Australia	Yes	Yes	Yes

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> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Importantly, the Bolar exemption is equally applicable to generic and branded pharmaceuticals, medical devices, biologics, and biosimiliars and exempts a wide variety of activities reasonably related to gaining information relevant to gaining FDA approval. While both pre- and post-approval activity can be exempt, only limited types of post-approval conduct is exempt.[1]

Bolar exemptions in Canada

Canada provides both a statutory and common law exemption to patent infringement for regulated drug products. The statutory exemption to patent infringement is found in Section 55.2(1) of the Canadian Patent Act which states that:

> It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

It is worth noting that this provision relates to regulatory approval for inventions in any technology area. Like the United States, the Canadian exemption extends to materials that are not submitted to a regulatory authority.

Bolar exemptions in Mexico

Mexican law similarly provides for a Bolar-like exemption, although such protection is available only when a patent is within eight years of expiration for a biologic product, or within three years for a small molecule. Unfortunately, neither the Mexican Institute of Industrial Property (IMPI) nor the Medicines Regulatory Agency (COFEPRIS) have provided any guidance on whether small quantities of active pharmaceutical ingredients can be imported for conducting tests and trials necessary for applying for a marketing authorization in Mexico.

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[1] See, *Momenta Pharms., Inc. v. Teva Pharms. USA Inc.*, 809 F.3d 610 (Fed. Cir. 2015), *cert. denied sub nom*. *Amphastar Pharms., Inc. v. Momenta Pharms., Inc.*, 137 S. Ct. 68 (2016).

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Bolar exemption in Europe

The Bolar exemption is governed by European Directive 2001/83/EC on the Community Code relating to medicinal products for human use. Article 10(6) excludes from infringement of patent rights or supplementary protection certificates (SPCs): "Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4." Paragraphs 1-4, i.e. Articles 10(1)-(4) of the Directive, concern the provision of data during the marketing approval process.[1]

The exact language, scope and interpretation of Bolar exemptions vary across Europe. Generally speaking, countries can be divided into two categories, (1) those countries where the exemption is limited to activities relating to marketing approval of generic medicines, bioequivalents and biosimilars, such as Belgium, Cyprus, Ireland, Netherlands and Sweden; and (2) those countries that more broadly exempt any act required for marketing approval, as well as acts relating to innovative medicines, such as Austria, Bulgaria, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, the UK, and Spain, as well as non-EU states Norway and Switzerland.[2]

Bolar exemptions in Asia

Bolar-type exemptions are prevalent in the national patent laws of many Asian countries. The scope of exemption varies significantly from state to state. For example, Pakistan provides Bolar-type provisions for research intended to be submitted to authorities in the country, while India more broadly exempts acts relating to the development and submission of information required by law "in India or in a country other than India." A similar exemption is also available in the Philippines in the Universally Accessible Cheaper and Quality Medicines Act of 2008. In contrast, the scope of the Bolar defense is narrower in Singapore, and is limited to clinical testing to meet requirements for marketing approval in that country alone.[3]

The types of products covered by Bolar-like legislation also vary across Asia. Some countries limit the exemption to drugs and medicines — such as Malaysia, the Philippines, and Thailand. Others, such as Vietnam extend the exemption to any product requiring regulatory approval, while Chinese law expressly covers a "patented medical apparatus" as well as a patented medicine.[4]

Australia and New Zealand also have Bolar exemptions. Australia's exemption does not include medical or therapeutic devices, but does include acts undertaken to obtain regulatory approval in a foreign country. Similarly, New Zealand legislation exempts acts related to the development and

submission of information required under New Zealand law or the law of any other country, but more broadly covers any regulated product.[5]

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[1] https://www.lexology.com/library/detail.aspx?g=4c4c2131-b897-44c2-8651-60bec32c6f50
[2] http://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html
[3] *Id.*
[4] *Id.*
[5] *Id.*

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Argentina	No[3]	n/a	n/a
Australia	Yes	Yes	Yes
Austria	Yes	Arguable[4]	Arguable[4]
Belgium	Yes	No	No
Brazil	Yes	Yes	Yes
Bulgaria	Yes	Not clear	Not clear
Canada	Yes	Yes	Yes
Chile	No	n/a	n/a
China	Yes[6]	Not clear	Not clear
Croatia	Yes	Yes	Not clear
Czech Republic	Yes	Yes	Yes
Denmark	Not yet[7]	-	-
Egypt[5]	Yes	Yes	Unclear
France	Yes	Arguable[4]	Arguable[4]
Germany	Yes	Yes	Yes
Hong Kong	No	n/a	n/a
Hungary	Yes	Arguable[4]	Not clear
India	Yes	Yes	Yes
Iran[5]	Yes	Yes	Unclear
Ireland	Yes	No	No
Israel	Yes	Yes	Not clear
Italy	Yes	Arguable[4]	Yes
Jordan[5]	Yes	Yes	Unclear
Korea	Yes?[8]	Not clear	Not clear
Latvia	Yes	Yes	Yes

Country	Recognizes Clinical Trial Exemption	Exemption Covers New Drugs as well as Generics/Biosimilars?[1]	Ability to Export Data for Authorization in Foreign Jurisdiction?[2]
Lebanon[5]	Yes	Yes	Unclear
Mexico	Yes	Yes	Yes
Morocco[5]	Yes	Yes	Unclear
Netherlands	Yes	Arguable[4]	No
New Zealand	Yes	Yes	Not clear
Philippines	Yes	Arguable[4]	Yes
Poland	Yes	Yes	Probably limited to EU-member states
Portugal	Yes	No	No
Romania	Yes	Yes	Yes
Russia	Yes	Yes	Not clear
Saudi Arabia[5]	Yes	Yes	Unclear
Singapore	Yes	Yes	Not clear
Slovakia	Yes	Yes	Yes
South Africa	Yes	Not clear	Not clear
Spain	Yes	Yes	Yes
Sweden	Yes	No	No
Switzerland	Yes	Yes	Yes
Taiwan[3,11]	No	n/a	n/a
Turkey	Yes	Yes	Yes
UAE[5]	Yes	Yes	Unclear
Ukraine	No	n/a	n/a
United Kingdom	Yes	Yes[9]	No
United States	Yes	Yes	Yes[10]

[1] This column addresses whether the clinical trial exemption is limited to abbreviated generic/biosimilar trials which rely on an innovator's data, or whether trials conducted on new drugs are exempt as well.

[2] This column addresses whether the exemption is available in a first jurisdiction if the clinical trial is conducted in the first jurisdiction and the data generated is exported to a foreign jurisdiction for authorization in the foreign jurisdiction.

[3] Exemption only recognized for non-commercial experimentation

[4] Is arguable but not specifically addressed by statute

[5] MENA requirements

[6] Based on judicially-created law. A statutorily created provision went into effect on October 1, 2009.

[7] Pursuant to the EU directive, a new law on pharmaceuticals was introduced, however it did not contain the Bolar provision of Article 10(6). The provision was to be introduced into a revised Danish Patents Act.

[8] Korean law is largely modeled on Japanese law which judicially recognizes a clinical trial exemption. However, as of December 19, 2008 there is no Korean case law on point.

[9] Exemption in UK extended to brand pharmaceuticals

[10] Provided the activity is objectively related to generating information for the US FDA

[11] Taiwan is working on a proposed amendment to their Patent Act that would provide an exemption for clinical trials

*This document is based on information provided by local counsel in various countries. It does not constitute a legal opinion. Prior to commencing activities in any country, a legal opinion should be obtained from the relevant local associate based on the specific facts.