

Report Q202

in the name of the Israeli Group
by Tal BAND

The impact of public health issues on exclusive patent rights

Questions

1) Analysis of current law and case law

- 1) *Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?*

In 1998 the Patents Law, 1967 was amended to allow for an experimental use exception as well as a Bolar-type exception. The same amendment also made provisions for patent term extensions.

The experimental use exception stipulates that “an experimental act in connection with the invention, the objective of which is to improve the invention or to develop another invention” does not amount to patent infringement. Experimental use of this nature is allowed for commercial purposes as well as for purposes which are purely academic.

- 2) *Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee’s consent for the purpose of obtaining approval of a generic product be covered by the research exception?*

The Bolar-type exception introduced into the Patents Law in 1998 allows for otherwise infringing experimental acts if they form part of an effort to obtain a marketing licence for a patented product following the expiry of the patent. Said licence may be an Israeli licence or a licence issued in other countries which implement Bolar-type exceptions. Any products manufactured prior to the expiry of the patent may not be used – whether during or after the patent term – for any other purpose save for obtaining the licence, i.e., stockpiling patented products for distribution following expiration of the patent is not permitted.

The Bolar-type exception relates to any product, the marketing of which is conditional upon the receipt of a certificate, permit or any other regulatory document.

- 3) *Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?*

Some uncertainty exists regarding the legality of parallel imports of patented products. In the past, district courts have deemed parallel importation of patented products as constituting patent infringement. However, in a later Supreme Court decision, it was noted, in an

obiter dictum, that the doctrine of international exhaustion should apply to patent rights. A recent district court decision applied international exhaustion with regard to design rights and allowed the parallel importation of goods protected by a registered design (including translated user manuals).

- 4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

The Patents Law permits the use of a patent on a non-commercial scale, for non-commercial purposes. This has been construed to mean personal use of the patent, bearing no profits. The personal importation of patented medicine for personal consumption on a reasonable scale may satisfy this condition, although there is no case law on the particular subject.

- 5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?*

N/A.

- 6) *Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.*

Compulsory licences are available under the Patents Law in cases where a patentee abuses his monopoly, i.e. fails to supply the demand for the patented product in Israel on reasonable terms or stipulates conditions for the supply, production or licensing of his invention which are unfair under the circumstances, do not take into account the public interest and arise essentially due to the existence of the patent. A compulsory licence cannot be obtained prior to three years from the grant of the patent or four years from the filing of the patent application, whichever is the later.

When a compulsory licence is insufficient to prevent the patentee's abuse of his monopoly, the patent may be revoked. We are not aware of any such precedent.

In the past, the Patents Law perceived the public interest in the exploitation of a patented invention by way of domestic manufacture as a major consideration, so that lack of "local working" would be relevant for granting a compulsory licence. However, the scope of compulsory licences was not restricted to manufacture for the domestic market. The Patents Law has since been amended to conform with Article 27(1) TRIPS, so that lack of domestic manufacture does not constitute a ground for obtaining a compulsory licence. Additionally, in accordance with Article 31(f) TRIPS, compulsory licences are allowed predominantly for the supply of the domestic market.

In the past, the Patents Law contained special provisions that eased the obtainment of compulsory licences for medical products, processes and devices, for the purpose of guaranteeing "a reasonable quantity of medical supplies" and regardless of whether or not the patentee abuses his monopoly. However, those provisions were repealed in 1999 in order to conform with Article 31(b) TRIPS. Prior to the repeal of those provisions, several compulsory licences were granted in Israel in order to facilitate the domestic manufacture of pharmaceuticals and ensure their supply, including:

- In 1995 Bio-Technology General (Israel) Ltd. obtained a compulsory licence from Biogen Inc. for a patent covering Hepatitis B diagnosis and vaccination, based on a recombinant HBV antigen.

- In 1989 Agis Ltd. obtained a compulsory licence from Bayer Aktiengesellschaft for a patent relating to Bifonazole, an anti-fungal medication.
- In 1988 Agis Ltd. obtained a compulsory licence from Fisons Plc. for several patents relating to pharmaceutical preparations for the treatment of asthma.
- In 1984 Abic Ltd. obtained a compulsory licence from Ciba Geigy A.G. for a patent relating to Diclofenac Sodium, a non-steroidal anti-inflammatory drug (NSAID).
- In 1983 Teva Pharmaceutical Industries Ltd. and others obtained a compulsory licence from Farbwerke Hoechst A.G. for a patent covering Glibenclamide, an anti-diabetic drug.
- In 1972 Assia Chemical Industries Ltd. obtained a compulsory licence from Beecham Group Limited, England for two patents relating to the antibiotic Ampicillin.
- In 1970 Assia Chemical Industries Ltd. obtained a compulsory licence from Boots Pure Drug Company Ltd. for a patent relating to derivatives of Acetanilide, a now obsolete drug with analgesic and antipyretic properties.

7) *Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003? Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.*

Israel was one of the first ten WTO members to ratify Article 31bis TRIPS. The Patents Law has yet to be amended accordingly. In any event, Israel has agreed to restrict importation under the Doha Declaration only to situations of national emergency or other circumstances of extreme urgency.

8) *Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?*

The Patents Law allows the relevant Minister to permit exploitation of an invention, whether patented or not, through governmental departments and state enterprises or agencies, if such exploitation is necessary for interests of national security or for the maintenance of essential supplies and services. Third parties operating under a contract with the state may also be granted a permit to exploit an invention, in order to facilitate consummation of such contract, solely for the above purposes and as required by the state. In the absence of an understanding, a statutory committee may set the royalties payable to the patentee or to the exclusive licensee.

9) *Is the government allowed to expropriate a patent and, if so, under which conditions?*

The Minister of Defence may restrict the publication of patent applications and the granting of patents in the interests of national security. The Minister of Defence may similarly restrict inventions essential to the development of nuclear energy in Israel or whose publication may harm nuclear research in Israel. Furthermore, permanent residents of Israel or other persons owning allegiance to the state wishing to file patent applications of this nature, must do so in Israel first, thereby allowing the authorities to restrict the applications before they are filed abroad. A statutory committee may decide on the compensation payable to the owner of any such patent application.

10) *If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.*

The Pharmacists' Ordinance, 1981 allows for the parallel importation of pharmaceutical preparations. In the past, only the original sponsor of a drug could import it into Israel. Some leeway was provided to non-profit medical institutions, allowing them to independently import pharmaceutical preparations. However, since 1999, it is possible to import pharmaceutical preparations by reliance on the original entry in the Drug Registry. The importer is required to obtain certification that his goods are comparable to the registered drug. Of course, the Pharmacists' Ordinance has no bearing on patent rights.

II) Proposals for adoption of uniform rules

- 1) *Should patent law provide for*
 - *research and experimental use exception;*
Yes.
 - *Bolar exception;*
Yes.
 - *parallel import of patented medicines;*
 - *individual prescriptions exception;*
Yes.
 - *medical treatment defence;*
 - *compulsory licensing;*
Yes.
 - *expropriation;*
Yes.
 - *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*
If so, under what circumstances? If not, why not?
- 2) *Do you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

Harmonize the rules on patents of selection, review and assess practices of the pharmaceutical industries aimed at "evergreening".
- 3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?*