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Report Q202

in the name of the Irish Group
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The impact of public health issues on exclusive patent rights

Questions

I) 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?

Under Section 42(b) of the Irish Patents Act, 1992, the rights conferred by a patent shall not extend to acts done for experimental purposes relating to the subject-matter of the relevant patented invention.

However, no guidance was provided in Irish legislation as to what exactly constitutes "experimental use". Accordingly, we would look to the case law for guidance in this regard. There is little case law in Ireland in the area of patents and the Irish Courts would be guided by the decisions of the English courts in this regard.

In the United Kingdom a narrow construction of the experimental use exemption has traditionally been preferred. For example, the Court of Appeal in *Monsanto v Stauffer* (1984) indicated that clinical trials aimed at obtaining regulatory approval constituted patent infringement.

In *Smith Kline & French -v- Evans Medical Limited*, the Court held that experiments carried out with a commercial end in view may be covered provided that the purpose of the experiments had to relate to the subject-matter in suit in the sense of having a real and direct connection with the subject-matter. Thus, in this case the Court held that experiments on material covered by a patent were not being carried out to investigate the invention of that patent but for the purposes of litigation in order to invalidate the patent and their acts did not fall under the "experimental use" exemption.

The German courts, on the other hand, in *Clinical Trials I* and *Clinical Trials II* (1994) held that tests whose aim is to yield new knowledge on the patented subject matter are non-infringing even where they have a collateral commercial purpose.

There is one major exception to the experimental use exemption under Irish law, namely the Bolar type exemption.

Like Ireland, most Member States of the EU exempt "experimental uses" of patents from patent infringement suits. As indicated above, the Member States adopted different interpretations of "experimental use" and accordingly the position in relation to undertaking tests and trials for the purpose of obtaining a future marketing authorisation differs across the EU.

The EU introduced Community-wide Bolar exemptions under Directive 2004/27/EC (with respect to medicinal products for human use) and Directive 2004/28/EC (with respect to

veterinary medicinal products), which were implemented by all Member States on October 30, 2005.

Statutory Instrument No. 50 of 2006 gives effect to Directive 2004/27/EC and involved insertion of a new subsection (g) into Section 42 of the Patents Act 1992, which reads as follows:

The rights conferred by a patent shall not extend to:

g) acts done relating to the subject matter of the relevant patented invention which consist of:

   i) acts done in conducting the studies, tests and trials which are necessary for and are conducted with a view to satisfying the application requirements under Community law for a marketing authorization for a medicinal product for human use; or

   ii) acts done in conducting the studies, tests and trials which are necessary for and are conducted with a view to satisfying the application requirements under Community law for a marketing authorization for a medicinal product for human use; or

   iii) any other act which is required as a consequence of the acts referred to in subparagraph (i) or (ii) for the purposes specified in those subparagraphs, as appropriate.

The key point to note about this new exemption is that it only applies to experimental activities carried out by generic manufacturers with a view to obtaining a marketing authorisation for a generic drug. It does not entitle innovative companies to make experimental uses of patented medicines or research tools for the purpose of seeking a marketing authorisation for a **new** medicinal product. As the existing experimental use exception under section 42(b) of the Patents Act 1992 is generally viewed as excluding experimental uses that have a commercial purpose, innovative pharmaceutical companies based in Ireland are being placed in an anomalous position: generic companies will be able to conduct experiments and trials necessary for obtaining marketing authorisation of generic medicines, but innovative companies will probably not have the same entitlement with respect to their new drugs.

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?*

Answered in Question 1 above.

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?*

The parallel importation of patented medicines, medical devices and such is permitted in Ireland in accordance with the Community Treaty. In order to fulfil the aims of the E.U. "single market", the ECJ has adopted what has come to be called the "exhaustion of rights" doctrine applied under what are now Articles 28 and 30 of the Community Treaty. Under this doctrine, the first marketing within the European Economic Area (EEA) of a product protected anywhere within the E.U. by an industrial property right "exhausts" that industrial property right, not only in the country of first sale, but also in any other country within the EEA, provided that such first marketing was carried out by the holder of that right or with his consent, either express or implied.

Simply put, this doctrine means that patent rights cannot be used to prevent the import of goods which have been marketed by the patentee or with his consent in another Member State.

The "exhaustion of rights" doctrine relies heavily upon the first sale having been made either by the rights holder or with his consent, express or implied. Thus, in *Pharmon-v-Hoechst*, where the first sale arose under a United Kingdom compulsory licence, the ECJ held that the product was not put on the market with the patentee's consent, so that infringement action could be brought under a parallel patent.

Likewise, where patents exist in some, but not all, E.U. States and the patentee has deliberately not granted licences under those patents, although a general know-how licence may have been granted, there is no exhaustion of right when goods manufactured under the know-how licence are imported into a State where no patent licence was granted, again because consent cannot exist where a licence had not been given. Nor is a refusal to license patents in itself a breach of Articles 81 and 82 (anti-competition) of the Community Treaty unless that is an aspect of an overall anti-competitive conduct, see *Sandvik-v-Pfiffner*.

In *Allen & Hanbury-v-Generics*, the "licence of right" provisions of Section 46 of the U.K. Patents Act, 1977, were considered equivalent to the grant of compulsory licences, the "licence of right" endorsement had in this case been made involuntarily. The position could be different if the patentee elects so to endorse his patent.

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

Under Section 42(c) of the Irish Patents Act, 1992, no infringement arises where there is extemporaneous preparation of a medicine in a pharmacy for individual cases where such is in accordance with a medical prescription issued by a registered medical practitioner or acts concerning the medicine so prepared.

This provision excludes the extemporaneous preparation in a pharmacy of medicine for an individual to a prescription by a registered medical practitioner or dentist. "Extemporaneous" is not defined, but may be taken as meaning as and when required, so that medicines prepared for stock in advance of a specific need therefor arising are probably not exempt; and, in any case, the preparation must be "for an individual". It would appear that veterinary preparations are not exempted by the provision as such a preparation would not be provided for an individual, this presumably meaning a human being, nor would it be provided by a "medical or dental practitioner", at least by a person practicing as such. Anyway, it is currently rare for a pharmacy itself to prepare a medicine since medicinal products are normally supplied to the pharmacy in a pre-packed condition. Thus, the acts exempted under the provision are probably of little consequence.

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?*

Not applicable.

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.*

Under Section 70(1) of the Irish Patents Act, 1992, and as amended by the Patents Amendment Act, 2006, at any time after the expiration of the period of three years, or such other period

as may be prescribed, beginning on the date of the publication of notice of grant of a patent any person may apply to the Controller for a licence under the patent, or for an entry in the register to the effect that licences under the patent are to be available as of right, on any or all of the following grounds:

a) that:

   i) a demand in the State for the subject matter of the patent is not being met or is not being met on reasonable terms; or

   ii) a demand in the State for a product which is protected by the patent is being met by importation other than from a member of the World Trade Organisation;

b) that the establishment or development of commercial or industrial activities in the State is unfairly prejudiced.

The Group is not currently aware of any compulsory licences granted in Ireland for the domestic manufacture and supply of pharmaceutical products since Ireland became a member of the WTO Agreement (including TRIPS) on January 1, 1995.

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.

The Irish Patents Act, 1992, as amended by the Patents (Amendment) Act, 2006, does not contain any provision that is equivalent to Article 31*bis* of the TRIPS Agreement.

However, Regulation 816/2006 of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems has now been adopted. Notice of this Regulation appeared in the Official Journal on 9th June 2006 and the Regulation entered into force on 29 June 2006.

The Regulation enables the manufacture of patented pharmaceutical products under license by someone other than the patent holder for export to countries with public health problems.

Most national laws do not allow compulsory licenses for export because, under Article 31 (f) of the TRIPS Agreement, products made under compulsory licensing must be "predominantly for the supply of the domestic market." The Regulation implements at EU level the WTO General Council Decision of 30 August 2003 which sets out a mechanism to allow export of medicines made under a compulsory licence to poor countries.

The Regulation prohibits re-importation into the EU of medicines produced under the compulsory licence system and provides for customs authorities to take action against goods being re-imported. Poor countries which are not members of the WTO may also take part in the scheme.

The Group is not currently aware of any compulsory licences granted in Ireland for the importation or exportation of pharmaceutical products.

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?

Under Section 77(1) of the Irish Patents Act, 1992, it is permissible for a Minister of the government, his officers, servants, agents or persons authorised in writing, to use patented inventions for the service of the State and without the consent of the patentee. Under Section 77(2), certain acts which would otherwise amount to an infringement are not to be considered

as such. Service of the State is broadly defined to mean a service financed out of moneys charged on or advanced out of the central fund or moneys provided by the Oireachtas or by a local authority for the purposed of the Local Government Act, 1941.

The TRIPS Agreement recognises that a State may, in certain circumstances, use a patented invention without the authority of the right holder and on terms which include the right to be paid adequate remuneration taking into account the economic value of the authorisation. Under Section 77(6), the terms governing State use are agreed between the parties or failing which, the matter is referred to the High Court which in turn can refer the whole matter or any question or issue of fact to an arbitrator.

Under Section 77(4), if the invention prior to the filing or priority date has been recorded in a document by, or been tried by or on behalf of a Minister, then the State may use such royalty free or without any other payment. Evidence of such documentary recordal or the trial may be given to counsel representing the patent applicant/proprietor or to any agreed independent expert where the Minister determines that such disclosure would be detrimental to the public interest.

Under Section 77(8), the rights to State use include a power to dispose of, or sell, or offer to dispose of or sell, any products made in pursuance of such a right which are no longer required for the services of the State. Section 77(9) covers any persons acquiring such products.

There are extended provisions for State use during a period where there are in existence exceptional circumstances and it is desirable in the interests of the public. In such circumstances, the government may by order empower the State to use the invention for any purpose which appears to be necessary or expedient for one or more stated reasons which are set out in Section 78 of the Irish Patents Act, 1992.

These reasons include to ensure public safety and the preservation of the State, the maintenance and sufficiency of supplies and services essential to the life or well-being of the community and for assisting in the relief or suffering in any country outside of the State that is in grave distress. However, included in the reasons are broadly stated objectives such as for promoting the productivity of commerce and industry, including agriculture.

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

Answered in Question 8.

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.*

There are no provisions under Irish patent law that recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises that have not already been discussed above.

II) Proposals for adoption of uniform rules

1) *Should patent law provide for*

- *research and experimental use exception;*
- *Bolar exception;*
- *parallel import of patented medicines;*
- *individual prescriptions exception;*
- *medical treatment defence;*
- *compulsory licensing;*
- *expropriation;*

– *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?

As indicated in the answers to the questions above, Irish patent law already provides for the research and experimental use exception; Bolar exemption; parallel import of patented medicines; individual prescriptions exception; compulsory licensing; and expropriation of patents. The medical treatment defence is not applicable to Irish or European patent law as methods of medical treatment are unpatentable and the Group would lend its support to any proposed uniform legal provisions that would render methods of medical treatment unpatentable.

The research and experimental use exception, Bolar exemption, parallel import of patented medicines; individual prescriptions exception are already uniformly adopted in patent law across the EEA. The Group would be in favour of the introduction of similar provisions under the TRIPS Agreement or the Patent Co-operation Treaty.

However, the Group is of the view that it would appear to be somewhat more difficult to introduce uniform rules under patent law governing the parallel import of patented medicines as parallel importation of patented medicines involves complex economic issues that would be difficult to encompass uniformly under patent law.

With regard to compulsory licensing, the provision under Article 31bis would appear to be adequate for the time being.

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?*

At present, it is difficult to envisage other ways other than limitations of patent rights that could facilitate access to medicines, diagnostics, medical devices and the like.

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?*

Answered in Proposal 1 above.

Summary

Provisions exist under the Irish Patents Act, 1992, and European law for the research and experimental use exception; the so-called Bolar exemption; the parallel import of patented medicines; the individual prescriptions exception; compulsory licensing; and expropriation of patents. All of the abovementioned provisions facilitate access to medicines, diagnostics, medical devices and the like. The Group would lend its support to any proposed uniform legal provisions that would encompass the research and experimental use exception; the so-called Bolar exemption; and the individual prescriptions exception. Methods of medical treatment are unpatentable under Irish and European patent law and the Group would lend its support to any proposed uniform legal provisions that would render methods of medical treatment unpatentable.